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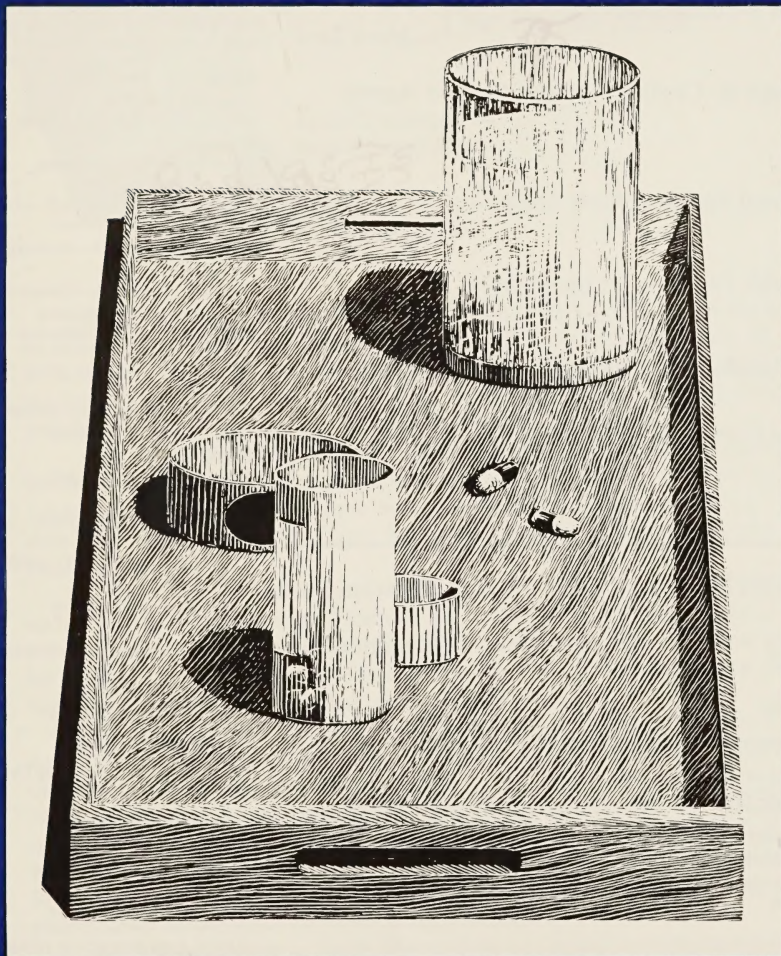
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The Maryland Pharmacist

VOL. 67

January, 1991

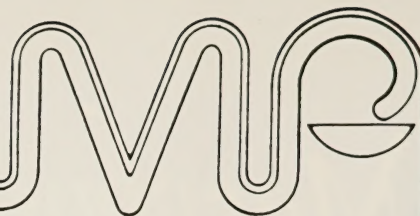
No. 1



*MPhA Mid-Year Educational Seminar
February 10, 1991
Loews Annapolis Hotel*

THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET
BALTIMORE MARYLAND 21201
TELEPHONE 301/727-0746



JANUARY, 1991

VOL. 67

NO. 1

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The Maryland Pharmacist (ISSN 0025-4347) is published monthly by the Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201. Annual Subscription — United States and foreign, \$10 a year; single copies, \$1.50. Members of the Maryland Pharmacists Association receive The Maryland Pharmacist each month as part of their annual membership dues. Entered as second class matter at Baltimore, Maryland and additional mailing offices. Postmaster: send address changes to: The Maryland Pharmacist, 650 West Lombard Street, Baltimore, Maryland 21201.

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Are We Learning The Right Stuff?

Continuing education for pharmacists has long been hailed as the means to assuring continued competence of the profession's practitioners. In fact, MPhA used this argument in 1986 to secure passage of the mandatory continuing education law in Maryland. But are we really assuring competence or just jumping through regulatory hoops to keep our licenses?

We've all attended seminars where half the attendees were asleep and the other half were carrying on conversations with their friends. We've all attended seminars where the topic was nothing more than an hour-long "commercial" for the industry's latest innovation. Is this education? Is this what pharmacists need?

One of my personal goals as President is to assure that the programs sponsored by the Maryland Pharmacists Association are timely and contain information that can be used by pharmacists. MPhA wants to see open eyes at its seminars. That's why we have been paying special attention to the evaluation forms completed at the end of each of our programs.

To meet the goal, our Mid-Year Educational Seminar will have a clinically oriented program on new drugs and drug therapies *and* a personal development program on understanding your personality and how to work with others. Programs for our Annual Convention include seminars on legal liability of pharmacists and time management in addition to programs on drug and disease issues. I am also pleased to report that one of our affiliates, the Baltimore Metropolitan Pharmaceutical Association, is developing a seminar for young pharmacists on personal financial management.

MPhA wants you to learn. We want you to enjoy continuing education, not endure it. Please let us know what *you* want by calling our office or writing your interests on our evaluation forms.

I look forward to seeing each of you at our upcoming Mid-Year!

Mark A. Levi, P.D.

President

Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Correspondence Course

New Drugs, Part II: Central Nervous System Agents

by Thomas A. Gossel, R.Ph., Ph.D.
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and

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Goals

The goals of this lesson are to identify and discuss new drugs approved by FDA and/or marketed during late 1989 and 1990.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge of the drugs discussed by pharmacologic and ther-



Gossel



Wuest

apeutic classification;

2. choose the indications, mechanism of action, benefits and limitations of the drugs discussed;

3. identify adverse effects and drug interactions associated with the drugs; and

4. demonstrate an ability to counsel patients on these new drugs.

An average of 21.7 new molecular entity drugs were approved each year throughout the 1980s. Drugs that were approved and/or marketed since late 1989, and are active on the central nervous system, are discussed in this article. The number-letter designation that follows first mention of the generic name is FDA's classification, assigned at the time the manufacturer requested a New Drug Application. All drugs in this article are "1" (new chemical entities). The letters include: A (significant therapeutic gain), B (modest therapeutic gain), and C (little or no therapeutic gain), when compared to previously available therapy for the same indication.

Antiparkinson Drugs

Pergolide (1B; Permax). Pergolide, like bromocriptine (Parlodel), is an agonist for dopamine receptors in the central nervous system, most specifically, the extrapyramidal system. It is especially beneficial as adjunctive therapy in advanced Parkinson's disease when response to levodopa is deteriorating.

Parkinsonism refers to a number of neurological disorders that affect a per-

son's ability to properly control muscular movement. It is a collection of disorders that range from akinesia (abnormal absence of movements) to dyskinesia (impairment of the power of muscle movement; sometimes referred to as shaking palsy).

The pathologic problem is believed to be an imbalance of neurotransmitters, primarily dopamine and acetylcholine, that control nerve impulses in the extrapyramidal system, the area in the brainstem that coordinates muscular motor movement. The basic problem for many patients is that they do not produce sufficient dopamine in that area.

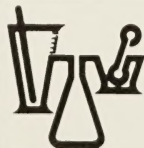
The treatment of choice for Parkinsonism is levodopa, given as the combination levodopa/carbidopa (Sine-met). Dopamine itself cannot be used because it does not cross the blood brain barrier from peripheral circulation to the brainstem where it is needed to correct the problem.

Levodopa, which does cross, is the immediate metabolic precursor to dopamine. It is metabolized into dopamine by the enzyme dopa decarboxylase. This can occur in the periphery to excessive degree leading to irritating and uncomfortable side effects and inadequate therapeutic action.

Carbidopa is a dopa decarboxylase inhibitor, and prevents peripheral conversion of levodopa to dopamine, increasing the amount available for transport into the central nervous system.

After several years of therapy, patients may experience a "wearing-off" effect so that each dose becomes less active. Others suffer an "on-off" response in that symptom relief alternates with inactivity. Pergolide and selegiline (Eldepryl) are indicated as adjunctive therapy to overcome these problems, and improve the effectiveness of levodopa/carbidopa.

Pergolide, like bromocriptine, is an ergot derivative that is a direct dopamine agonist for receptors in the CNS.



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This means that these agents, when they react with physiologically active areas on the nerve cells within the CNS, elicit the same response as dopamine. Pergolide decreases the on-off phenomenon of levodopa/carbidopa, and may lead to reduction in the amount of levodopa needed for some patients.

There can be significant adverse effects with pergolide. Among these are nausea and indigestion, diarrhea or constipation, nasal stuffiness, orthostatic hypotension, dizziness, confusion, insomnia or somnolence, and hallucinations. The latter effect is reported to be the leading cause of dropout from therapy.

While no overt drug interactions have been reported, it can be anticipated that dopamine antagonists, such as phenothiazines, haloperidol and metoclopramide may interfere with pergolide. It is also so highly protein bound, that pergolide may displace other drugs from such binding to increase their effects.

To minimize the chance of orthostatic hypotension during initiation of therapy, dosage should be titrated upward from a daily dose of 0.05 mg, possibly to 2 mg over a two- or three-week period. Some patients may require 1 mg three times a day for optimal results. To allow for the gradual titration, Permax is available in 0.05, 0.25 and 1 mg tablets.

Selegiline (1B; Eldepryl). Selegiline inhibits the enzyme monoamine oxidase (MAO). It acts preferentially on one form, termed MAO-B. Selegiline can achieve nearly complete inhibition of MAO-B with doses insufficient to inhibit MAO-A.

Its mechanism of action is referred to as "suicide inhibition." This pharmacologic designation refers to drugs that possess a chemically reactive group which is selectively activated by the target enzyme to convert it to a highly reactive intermediate. The converted form, then, irreversibly binds to and inhibits the enzyme. In other words, selegiline binds with MAO and is converted to its reactive form which then renders MAO inactive. Only subsequent synthesis of new enzyme can replace it. Since synthesis of MAO is a slow process, selegiline generally does not lose its effectiveness with prolonged therapy.

The differentiation of MAO-A from MAO-B is important in understanding

why, at therapeutic doses, selegiline does not cause drug interactions characteristic of other MAO inhibitors (e.g., Marplan, Nardil, Parlane). These are nonselective inhibitors because they act on both types of MAO.

Briefly, MAO-A acts in the gut wall and liver. It exerts its greatest effect on endogenous serotonin, and tyramine (as well as other pressor amines) contained in food. MAO-A blockade can result in excessive absorption of dietary pressor amines, leading to massive vasoconstriction and death.

MAO-B is most closely associated with the metabolism of dopamine in the brain. An MAO-B selective drug like selegiline decreases dopamine destruction and increases its availability to overcome symptoms of Parkinsonism without causing the drug interactions. In doses higher than recommended (5 mg bid) selegiline loses its selectivity for MAO-B, so these interactions can, and have, occurred.

Much of the research on selegiline was conducted in Europe under the generic name deprenyl, so it is possible that it may be prescribed by that name in the U.S. Potential future indications include attention deficit disorder, narcolepsy, depression, Alzheimer's disease and the initial treatment of Parkinsonism. There is evidence that some patients respond to therapy early in the disease, thus delaying the need for levodopa/carbidopa, and reducing its dose when it is needed.

The recommended dosage as an adjunct to levodopa/carbidopa in patients with the wearing-off or on-off phenomena is 5 mg twice daily, with breakfast and lunch to lessen GI tract upset. Eldepryl is available in 5 mg tablets.

Clomipramine (1A; Anafranil). Its manufacturer originally sought approval for clomipramine (a chlorinated derivative of imipramine) as an antidepressant in 1975. The application was denied, based on its toxicity profile. The most significant was seizure activity reported at 0.7 percent, five times greater than other antidepressants.

Studies were continued outside the U.S. including investigation for the obsessive-compulsive disorder (OCD). Currently, clomipramine is marketed in approximately 70 countries for depression and/or OCD, and has been available in some for longer than 20 years. On approval in the U.S., clomipramine became the agent of choice

for OCD.

Chronic obsessive compulsive disorders reportedly affect over 4,000,000 Americans. Their exact cause is not known, but the current theory is that obsessions, compulsions, or both are caused by imbalances of neurotransmitters in the brain, most specifically, a deficiency of serotonin.

Patients with OCD, on the obsessive side, undergo repeated, unwanted thoughts that intrude into a "normal" thought pattern. These lead to distress, possibly extreme anxiety, because the person usually knows his thoughts are irrational, but cannot change them.

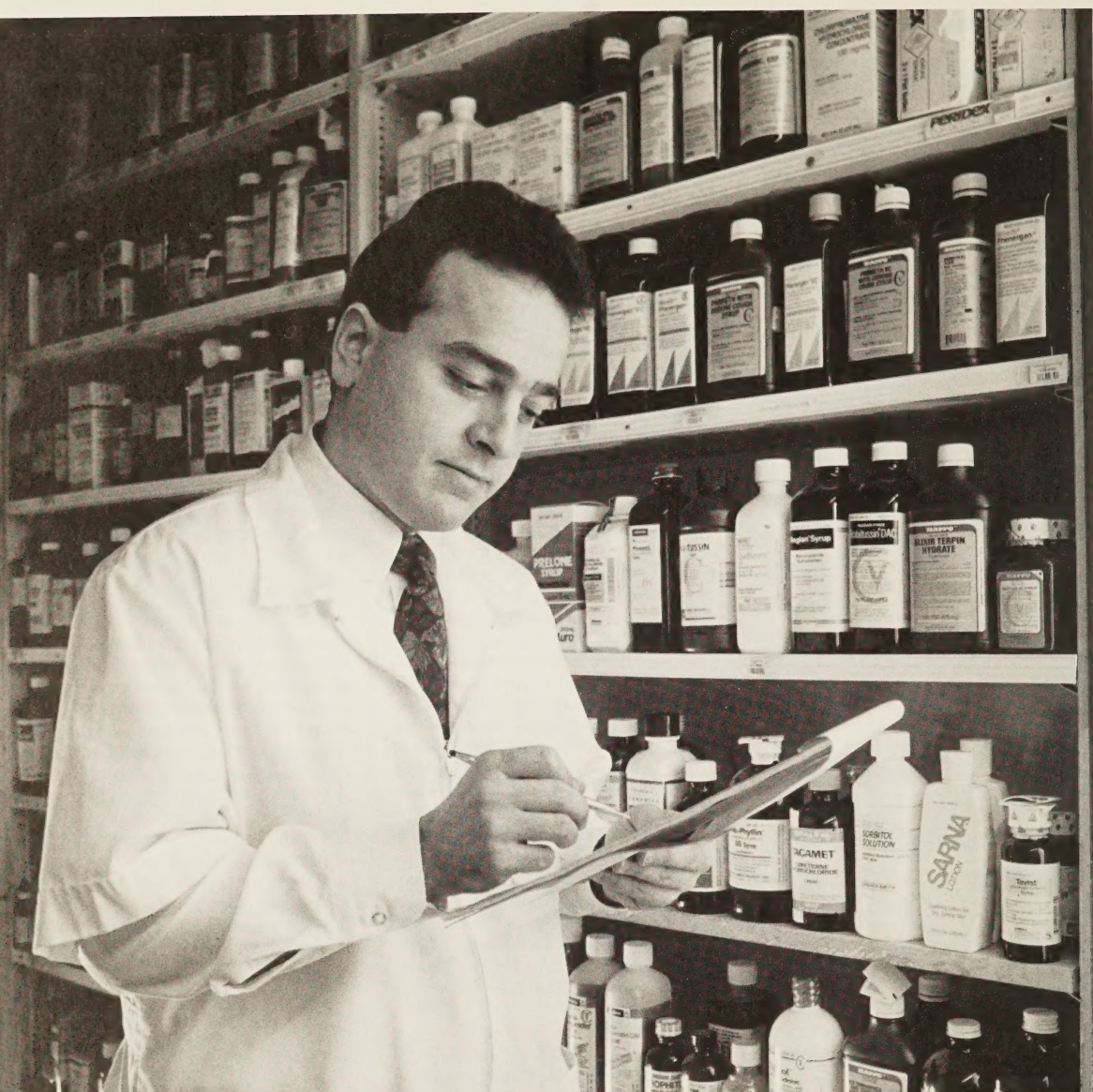
Among the more common compulsions are washing the hands or cleaning the home repeatedly, hoarding useless items, or incessantly talking and repeating the same words. When these interfere with the patient's occupational or social functioning, occupy a significant amount of time or cause undue distress, the person is a candidate for drug therapy.

The exact mechanism of action for clomipramine is unknown. There is evidence that its inhibition of serotonin uptake into nerve endings may be essential to its anti-OCD activity. This allows for more serotonin in the synaptic areas, thus reversing its deficiency. Clomipramine also blocks the reuptake of norepinephrine into storage areas and increases dopamine metabolism. The net result is that obsessions are eliminated and compulsive activity ceases.

The side effect profile is similar to other tricyclic antidepressants (TCAs), i.e., anticholinergic effects, orthostatic hypotension, CNS depression and tremor. It causes cardiac arrhythmias, like other TCAs, in toxic doses. Due to its high incidence of seizures, if clomipramine is to be administered to patients with a history of seizure disorders, it must be given with great caution.

The dosage regimen is 25 mg daily, gradually increased to 100 mg if needed, over a two-week period. Some patients may need 200 mg/day for symptom control. Doses over 200 mg daily exhibit increased side effects without increased therapeutic effect. Anafranil is available in 25, 50 and 75 mg capsules.

Bupropion (1B; Wellbutrin). Bupropion, which is therapeutically similar to, but chemically different from the tricyclic antidepressants, was mar-




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keted in late 1985. It was voluntarily withdrawn by its manufacturer in early 1986 due to a high occurrence of seizures in bulimic patients enrolled in a clinical trial. Since then, it has been evaluated for safety in more than 3000 patients. It was found that seizures resulted from doses higher than recommended, and are most common in patients prone to them, rather than patients without a history of seizures. Because of this, bupropion has been re-released for use in treatment of depression. It is contraindicated in patients with a history of seizures, and for treatment of bulimia.

The exact mechanism of action of bupropion is not known. It is not an MAO inhibitor. It does have weak uptake blocking action on norepinephrine and serotonin, and it inhibits reuptake of dopamine to some extent.

In contrast to traditional tricyclic antidepressants, bupropion does not block cholinergic, alpha-adrenergic or histaminergic receptors. Therefore, it causes fewer, if any, anticholinergic effects, orthostatic hypotension and drowsiness.

Bupropion causes mild stimulation, including insomnia and headache. In concert with its action on dopamine, precipitation of psychosis has been reported in a few patients. In contrast with TCAs, it causes fewer cardiovascular effects. Weight loss is often associated with therapy. Patients with mild congestive heart failure seem able to tolerate bupropion, even when they cannot tolerate other antidepressants.

Bupropion may be involved in several drug interactions. Because it is metabolized in the liver, drugs that enhance enzyme production and activity (e.g., carbamazepine, phenytoin, phenobarbital, rifampin) may decrease activity. Since both bupropion and levodopa affect dopamine activity, together they may cause increased side effects. The above interactions are hypothetical rather than proven. Concurrent use, or use within 14 days of an MAO inhibitor, is contraindicated.

The recommended dose of bupropion is 100 mg twice a day, morning and evening initially, increasing to 150 mg tid. The manufacturer strongly warns against individual doses greater than 150 mg, or daily doses greater than 450 mg due to the potential for seizures. Wellbutrin is available in 75 and 100 mg tablets.

Clozapine (1A; Clozaril). Clozapine was first synthesized in 1960 and marketed in Europe later that decade. Clinical trials were initiated in the U.S. in the 1970s. Reports of mortality due to agranulocytosis brought U.S. research to an almost complete halt. But interest continued, and the drug was given compassionate-use status for selected patients who did not improve on traditional therapy (chlorpromazine, etc.). After the potential for agranulocytosis became known, with proper monitoring, the occurrence dropped to 1 percent or less.

The manufacturer initially requested approval to market the drug in 1983. The request was denied because of a high incidence of agranulocytosis, and insufficient data to establish superior efficacy in light of known toxicity. With continued investigation, it was shown that after six months of therapy, up to 50 percent of schizophrenic patients taking clozapine, who were not helped by conventional therapy, improved. With proper WBC monitoring and drug withdrawal when signs of agranulocytosis appeared, the death rate decreased. None have been reported in this country. FDA approved the drug for treatment of patients with schizophrenia that do not respond to conventional therapy in September, 1989.

Clozapine joins loxapine (Loxitane) as a dibenzodiazepine antipsychotic. However, it differs therapeutically in that it does not cause the extrapyramidal (Parkinson-like) symptoms associated with other antipsychotics.

Clozapine's mechanism of action is believed to be due to blockade of dopamine in the brain (schizophrenia is thought to be caused by excessive dopamine levels). Clozapine has specific action on dopamine receptors in the limbic area, and this specificity may account for the lack of extrapyramidal symptoms relative to other antipsychotics which block dopamine in both the limbic and striatal areas. There are no documented cases of tardive dyskinesia, a condition usually seen in about 15 percent of patients on other antipsychotic drugs.

Other antipsychotic-induced afflictions not noted with clozapine are rigidity, mask-like facial expressions, or slowed movements. These effects are causes of discontinuation of therapy of other antipsychotic drugs.

Adverse effects of clozapine include hypersalivation, sedation, dizziness, tachycardia, orthostatic hypotension, fever and constipation. Hypersalivation and dizziness usually diminish after the first two weeks of therapy. Seizures were seen in approximately 5 percent of patients in clinical trials. These were dose-related and most prevalent in epileptic patients. While of concern, decreased seizure control is reported for all antipsychotic drugs.

The dosage of clozapine is 100 to 150 mg once or twice daily initially. This can be increased in 25 to 50 mg/day increments over a two-week period to reach an optimal dose of 300 to 450 mg daily. Rarely, patients may need 900 mg/day for full therapeutic effects. Clozaril is available in 25 and 100 mg tablets.

Propofol (1B; Diprivan). Propofol is an intravenous anesthetic for induction and maintenance of general anesthesia for most surgical procedures. It is used alone or in combination with other anesthetics. It has a rapid onset of action, usually within 30 to 40 seconds from start of infusion, and lasts 3 to 10 minutes, depending on the dose and rate of administration, which is monitored throughout surgery.

Propofol shares the adverse effects of other general anesthetics including pain at the site of injection, apnea, excitement and hypotension during induction, nausea and vomiting during recovery and residual sedation after surgery (less than previously available anesthetics).

This last property, i.e., more prompt recovery from anesthesia, is a marketing tool. During clinical trials, patients were able to return more quickly to self-care, thus requiring less monitoring by recovery room staff. They were also able to tolerate orally administered fluids faster and were alert sooner.

The dosage is individualized, usually 2 to 2.5 mg/kg averaging 40 mg every 10 seconds for induction, and 0.1 to 0.2 mg/kg/minute for maintenance of anesthesia. Diprivan is available in a concentration of 10 mg/mL in 20 mL glass ampules.

Ketorolac (1B; Toradol) This drug has analgesic, anti-inflammatory and antipyretic actions characteristic of

TABLE 1

Summary of Adverse Events in Two Multiple-Dose Efficacy Studies*

	Toradol 30 mg (n = 509)		Morphine 10 & 12 mg (n = 151)	
Number of Patients Reporting:**				
Any Body System/Any Adverse Event	197	(39%)	106	(70%)
Nervous System	116	(23%)	67	(44%)
Digestive System	66	(13%)	43	(28%)
Skin and Appendages	5	(1%)	21	(14%)
Injection Site	19	(4%)	11	(7%)
Cardiovascular System	18	(4%)	4	(3%)
Urogenital System	2	(<1%)	6	(4%)
Body as a Whole	8	(2%)	5	(3%)
Musculoskeletal System	2	(<1%)	3	(2%)
Metabolic/Nutritional Disorders	3	(1%)	2	(1%)
Respiratory System	4	(1%)	2	(1%)
Special Senses	6	(1%)	2	(1%)
Hemic and Lymphatic System	2	(<1%)	1	(1%)
Number of Patients Terminating Early Due to Adverse Events				
	35	(7%)	26	(17%)

*Excludes events considered probably not related to the treatment drug.

**A patient is counted once for a body system if he reports one or more complaints for that body system.

nonsteroidal anti-inflammatory drugs (NSAIDs) in general. Ketorolac inhibits the action of cyclooxygenase, which in turn, inhibits prostaglandin synthesis, relieving pain. Pain relief from ketorolac may be evident within 10 minutes of an intramuscular injection.

The drug is not an opioid. It therefore does not cause typical adverse effects characteristic of opioids. Patients receiving ketorolac have not developed tolerance to it, and drug discontinuation does not cause signs of withdrawal. Since it is only approved for short-term use, parenteral ketorolac is not indicated for treatment of rheumatoid disorders and no attempt was made to market it for fever reduction.

In controlled trials, ketorolac was associated with fewer adverse effects, and less discontinuance of therapy due to adverse effects, than either meperidine or morphine (Table 1). Adverse effects related to nervous and digestive symptoms are among the most common with both ketorolac and narcotics, but are reported twice as often with morphine than ketorolac.

Since ketorolac is an NSAID, it is synergistic to, and may be used concomitantly with, opioids. However,

they are incompatible and should not be mixed in the same syringe.

Ketorolac is contraindicated in persons with previous hypersensitivity to aspirin or other NSAIDs, or in patients who have experienced nasal polyps, angioedema, or bronchospasm caused by aspirin. Use in persons with impaired renal function or a history of kidney disease must be undertaken with caution and in reduced doses. Because it is reported to lead to fluid retention and edema, ketorolac should be used cautiously in patients with cardiac or hypertensive disorders.

Since it is not a scheduled drug, nurses and pharmacists are relieved of the paperwork of the Controlled Substance Act. This is an important marketing point.

The dosage is 30 to 60 mg by intramuscular injection initially, and 15 to 20 mg IM every 6 hours when needed, up to 120 mg daily. Toradol is available in 15 mg/mL and 30 mg/mL syringes containing 1 mL, and a 2 mL syringe with the 30 mg/mL concentration for a 60 mg dose.

Dezocine (1C; Dalgan). A new synthetic opioid agonist/antagonist, dezocine is an effective analgesic for pain of

surgery and cancer. In equipotent doses, it is comparable to morphine in efficacy and safety. Dezocine is claimed to cause fewer side effects than morphine with little or no abuse potential. Therefore, like ketorolac, it is not a controlled substance.

The drug joins butorphanol (Stadol), nalbuphine (Nubain) and pentazocaine (Talwin) in the category of analgesics with mixed agonist and antagonist effects. Its opioid antagonistic action is greater than pentazocine, but less than nalorphine. What little respiratory depression dezocine causes can be reversed with nalorphine.

The exact mechanism of action for analgesics has not yet been determined. The current theory is that when pain occurs it is due to chemicals released from affected cells. These stimulate nerve endings to initiate a series of events that the brain interprets as pain.

The discovery that opiates block receptors was made before the endogenous receptor-blocking substances were elucidated, so they have been given the name "opiate receptors." It is theorized that opioid analgesics bind at these receptor sites, and prevent the action of pain-inducing neurotransmitters, thus providing analgesia and also potential side effects. Four have been identified to date: delta, kappa, mu and sigma receptors.

Dezocine is claimed to be an ideal analgesic because it has high activity on the mu and delta opioid receptors, less activity on kappa receptors, and even less on sigma receptors than other agonist/antagonist opioids. Since action on kappa and sigma receptors is thought to be responsible for CNS effects associated with narcotic abuse, Dalgan will be marketed as the least-likely-to-be-abused opioid analgesic available.

The dosage is 5 to 10 mg intravenously or 10 to 15 mg intramuscularly every 3 to 4 hours with the dosage titrated to relieve the patient's pain. The maximum single dose is 20 mg with a recommended daily dosage limit of 120 mg. Dalgan is available in 5 mg/mL, 10 mg/mL and 15 mg/mL strengths.

Summary

This discussion of new drugs will be continued and concluded in Part III of this series.

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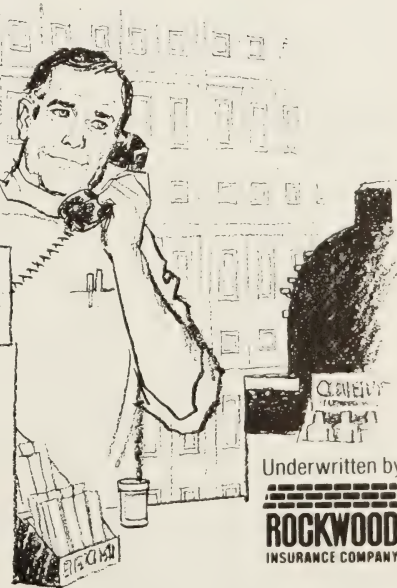
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National Coalition Urges Early Diagnosis of Gallstones

More options may be available for those patients with gallstones who don't want an operation, if their symptoms are diagnosed early, according to the Digestive Disease National Coalition (DDNC), which today launched a national education program about the disorder. Each year, 500,000 people undergo surgery to have their gallbladder removed.

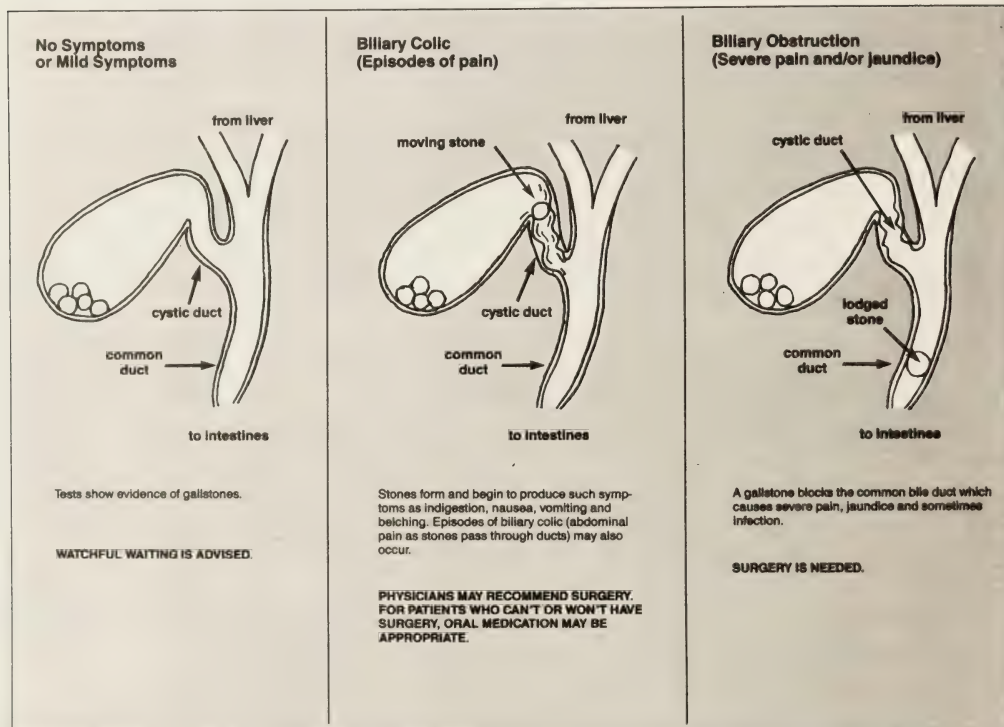
Called the Early Diagnosis of Gallstone Education (EDGE) Program, the DDNC campaign includes educational information designed to teach patients how to recognize the

symptoms of gallstone disease. These symptoms include gas, nausea, bloating and/or severe pain in the upper right abdomen. "Twenty-five million Americans have gallstones although not all require treatment. However, many of those patients with persistent symptoms may confuse the early warning signs with other ailments, and delay a doctor's assessment of the problem," said John Farrar, M.D., president of the DDNC, an association of voluntary, professional and corporate organizations devoted to digestive disease re-

search and education. "Because the symptoms are often the same as those from indigestion or ulcers, many people self-medicate with antacids," Dr. Farrar added. "Unfortunately, for a person with gallstones, antacids won't treat the problem."

If ignored, gallstones can progress in some patients to the point where stones pass through, and get stuck in the bile ducts, causing severe pain in the upper right side, jaundice and infection. At this stage, surgery to remove the gallbladder is the only option.

HOW GALLSTONES PROGRESS



A COMPARISON OF COMMON DIGESTIVE DISORDERS

Very often, the symptoms of gallstones are mistaken for those of indigestion (dyspepsia) and ulcers. If you have been taking antacids and/or medication for ulcers and indigestion, and your symptoms still persist, you may have gallstones. See your doctor.

GALLSTONES	INDIGESTION (DYSPEPSIA)	STOMACH ULCER
Bloating	Bloating	Bloating
Belching	Belching	Belching
Nausea	Nausea	Nausea
Vomiting	Vomiting	Vomiting
Abdominal Pain	—	Abdominal Pain
Jaundice	—	—
—	Pain in Lower Chest	—
—	Heartburn	—
—	—	Pain Between Meals
—	—	Bleeding

There are two types of gallstones. The most common type, cholesterol stones, occur when the liver secretes too much cholesterol into the bile, a greenish substance that aids in the digestion of fatty foods. This excess cholesterol crystallizes, forming solid lumps, or gallstones. The second type of gallstone is due to excess calcium and bile pigment.

Benefits of Early Diagnosis

"Most patients do not require treatment. In those that need therapy, surgery to remove the gallbladder is presently the most common treatment in many cases," Dr. Farrar said. "For those symptomatic patients diagnosed early with the right size and type of gall-

stones there may be a wider range of therapies to choose from. That's why, if symptoms persist, it's important to consult a doctor promptly."

One advantage of non-surgical therapies is that they may not interfere with a patient's lifestyle. Non-surgical treatments include oral dissolution with ursodiol. A naturally occurring bile acid, this medication is used to dissolve cholesterol stones less than three-quarters of an inch in diameter in symptomatic patients who can't or won't have surgery. The most common side effect is diarrhea, which occurs rarely. In up to half of the patients, gallstones may recur over a five year period. Patients may be retreated if symptoms recur.

Therapies still under investigation include:

- Shock wave lithotripsy (fragmenting stones with sound waves).
- Laparoscopic cholecystectomy (surgery to remove the gallbladder through a tube inserted into the lower abdomen).

"The treatment of gallstones has changed dramatically and so quickly in the last few years that it's not surprising to find out that people are confused," Dr. Farrar said. "The goal of EDGE is to make sure that people are aware of symptoms of gallstones and different treatment options."

Survey Reveals Lack of Knowledge

A national Gallup survey released today suggests that most American women's knowledge about gallstone disease—its symptoms, risk factors and treatments—is somewhat limited.

The survey of women between the ages of 40 and 60 showed that 56 percent did not know that being female placed them at a higher risk of developing gallstones than men. Approximately two-thirds of the 25 million Americans who have gallstones are women, although not all are symptomatic.

Other risk factors that increase the likelihood of developing gallstones include: being overweight or losing weight rapidly; having been pregnant; or having a family history of gallstone disease.

Gallstone Booklet Disseminated Via Toll-Free Hotline

To enable patients to communicate easily and more effectively with their physician about gallstones, the DDNC developed the patient booklet, "Your Gallstones: Diagnosis and Treatment." The booklet includes basic questions and answers about the disease and can be obtained by calling 1-800-695-EDGE, the toll-free hotline established by the DDNC.

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Oral Health Problems in the Elderly: Normal, Pathological and Drug-Induced

Michelle Andoll

The oral health status of the elderly population should be an important concern of all health practitioners. The oral cavity can be a window through which many diseases and drug side effects are seen. Certain characteristics of the mouth commonly seen in the elderly are now recognized as symptoms of some underlying disease or an adverse drug reaction and not merely the result of growing old. This paper addresses two drug induced complications commonly seen in the elderly; xerostomia and gingival hyperplasia, and the dental needs of the elderly.

In order to deliver adequate treatment to a patient, the findings of an oral examination must be correctly interpreted. For many years complaints such as dry mouth, altered taste sensation, tooth loss, and difficulty chewing were reduced to being a normal part of aging. Today there are ongoing studies being undertaken using new analytical methods based on evidence that such complaints are not normal and are due most likely to therapeutic drugs or a systemic disease.

Dry mouth or xerostomia is a common complaint of the elderly often described as being normal. Saliva plays a major role in maintaining good oral health. Saliva provides lubrication of the oral mucosa, buffers acid produced by bacteria, fights bacteria, mechanically cleans the cavity, mediates taste acuity and remineralizes teeth (Baum 1984). Given all these functions, it is easy to see why xerostomia can have significant implications to good oral health. Attempts in the past to study changes in saliva flow rates over an age range have been misleading and difficult to interpret. Saliva has several components and ion contents which complicates accurate measurement of saliva composition and flow rates. The type of secretions studied, the unknown optimum composition of saliva, the methods used to illicit salivation all are factors that complicate the study of saliva flow rates in any age group. What has been shown in some studies and is now being ac-

cepted until more studies are done is that there is no diminution in saliva flow or salivary gland function with increasing age in healthy, unmedicated subjects. Since saliva flow and production is under the control of the autonomic nervous system, it is easy to see that drugs or disease that alter this system may adversely affect salivation. Drugs may not only reduce flow rates but ion content and composition may also be affected. Radiation to the neck may also alter saliva flow rates by changing the structure of the salivary glands in the neck. It is, therefore, important to be cognizant of the medication and medical history of your patient and determine the probable cause of his xerostomia and do not dismiss it as the result of growing old.

Before now, gustatory function was believed to be reduced in the elderly but this is now being questioned for accuracy. While reports in the past (Arey 1935) have said to have seen a reduction in taste buds with increasing age, other more recent studies showed no such change (Arvidson 1979). Problems in measuring this function, similar to those associated with saliva flow, complicates the conduction of accurate studies. What qualities to study, which categories of gustatory ability should be studied and how to quantify and analyze this data are problems faced by those researchers wishing to further these studies.

Gross changes in gustatory function should be considered abnormal and poor oral health should be considered as the cause. Lack of oral hygiene often seen in nursing homes and institutions may leave food debris and bacteria in the mouth for long periods of time. This debris can cause unpleasant taste sensations and even cause a foul smelling discharge inside the mouth that contributes to the problem. When a patient complains that food does not taste the same anymore, that they no longer enjoy their favorite foods, or they stop eating, a problem should be suspected and their complaints be taken seriously.

The coordinated operation of the neuromuscular units in the face and oral cavity has many activities. Speech, posture, swallowing and mastication are all affected by oral motor function. Several pathological states may involve dysfunction of these muscles. Even edentulous patients are in need of these muscles to retain their prosthetic devices, speak and chew. Studies have shown that there may be some changes in the function of these facial muscles with increasing age. In one study it was shown that the elderly are capable of efficient mastication, but may require more time to prepare food for swallowing. This may be of importance when it bothers the patient to have to chew longer and the patient subsequently changes his food selection. If the circumferential muscles of the face become weak, drooling may result. There is some evidence that these muscles do weaken with increased age. Drooling is often a complaint of the elderly and may be due to muscle impairment. Drooling may also be due to a systemic disease or a therapeutic drug, such as phenothiazines, that cause tardive dyskinesia. Studies that monitored swallowing activity have shown no change with age (Feldman 1980), but there is significantly more dysfunction in the elderly who are medicated (Baum 1983). Studies of tongue function have shown some dysfunction with age. For some patients these problems may have consequences as minor as altered speech and bite injuries or be as severe as choking.

It is a well known observation that, as a result of good preventive dentistry and public health programs, more of the elderly population of the future will retain their natural teeth later in life. This, however, presents a new problem to the elderly. As gingival recession occurs over time, more of the tooth below the crown becomes exposed. If proper dental care is not continued throughout life, cervical caries and not coronal caries may become a problem for the elderly. Little is known about the prevalence of cervical caries or its epidemiology and prevention.

Periodontal disease, like caries is a bacterial infection. It may result in the destruction of soft connective tissue and bone. Little is known about the incidence of this disease in the elderly. It is known that the disease occurs mostly in the 20-50 age group. Whether cases seen in the elderly are the result of disease from earlier in life or a new case is not known. Both the occurrence and etiology of periodontal disease and dental caries in the elderly population need further study.

The oral mucosa, aside from taste buds, serve to protect the mouth from desiccation, infection, detrimental chemicals and thermal shock (Baum 1984). The oral mucosa may be compromised in the presence of systemic disease such as blood dyscrasias and endocrinopathies. Trauma and infection also adversely affect the oral mucosa. There is very little scientific data to support the belief that dryness and friability of the oral mucosa is a normal part of aging. This lack of evidence makes it difficult to draw any conclusions about what is normal or pathological in the elderly. What may occur

more frequently in the elderly to compromise their oral mucosa is traumatic injury. The elderly are at risk to damage their oral mucosa if they wear poorly fitted dentures or suffer from chronic irritation due to poorly cleaned appliances. Ulcerative damage to the mucosa and hyperplastic and erythematous tissue changes can occur from chronic irritation from dentures. Neoplasms of the oral cavity may also occur more frequently in the elderly and, therefore, carcinomas should be considered when diagnosing oral lesions in this population.

While some complaints or examination findings may be due to increasing age, most such findings could clearly be the result of some underlying problem. More meaningful and well conducted studies need to be done to determine which changes in the oral cavity seen in the elderly are normal changes with aging and those which are pathological. Until more is known, all complaints from an elderly patient should be investigated, its cause found and treated. Poorly fitting dentures, poor oral hygiene, carcinomas and systemic disease are all possible causes of oral health problems. Considering the large number of elderly people taking prescription drugs, one possible cause that should never be overlooked is an adverse drug reaction.

Therapeutic drug use may in many ways affect oral health. The effect may be minor or rather severe requiring separate treatment. Prescription drugs may cause dry mouth (xerostomia), gingival hyperplasia and altered taste sensations. Drugs such as phenothiazines known to produce tardive dyskinesia may cause oral problems by inhibiting oral motor function. The result may be difficulty chewing, speaking, and holding saliva inside the mouth. Clearly the effects prescription drugs may have on oral health are vast. Some drugs taken for systemic problems may have even beneficial effects on the periodontium. For instance, there is evidence that immunosuppressant drugs such as prednisone and azathioprine may reduce gingival inflammation even in patients with very high plaque levels (Been, Engel 1981). Non-steroidal anti-inflammatory drugs may help reduce alveolar bone loss and by reducing prostaglandin concentrations in the periodontal tissues, influence the response of the tissue to plaque (Seymour 1988).

Therapeutic drugs are known to cause two very distinct side effects to the oral cavity. Xerostomia and gingival hyperplasia are widely recognized as untoward effects of several medications. Patients receiving a medication capable of producing either of these side effects should be evaluated and educated about the potential problems.

Gingival hyperplasia is an overgrowth of the gingival and may be so severe that the crowns of the teeth may be covered. Phenytoin (Dilantin), an anti-convulsant, is the classic example of a drug causing gingival hyperplasia. It was first reported in the 1930's and it is estimated that it occurs in 50% of the patients taking phenytoin (Seymour 1988). The incidence is higher in the institutionalized population. Phenytoin induced hyperplasia most likely occurs in the first year of therapy.

The swelling will begin diffuse then coalesce. The tissues may appear coral to deep purple in color. Predisposing factors for phenytoin induced hyperplasia include poor oral hygiene and higher serum phenytoin levels (Little et al 1975). Factors such as immunosuppression, mouth breathing and other local factors in the mouth may somehow contribute to the incidence of gingival hyperplasia. The mechanism of phenytoin induced hyperplasia is not known. Several theories exist and most likely the hyperplasia is the result of direct effect of phenytoin metabolites on the tissues involved (Modeer et al 1980).

The use of phenytoin for a long period of time may cause osteomalacia secondary to an impairment of vitamin D metabolism (Stamp 1984). Phenytoin affects vitamin D metabolism by inducing the liver enzymes required to catabolize the vitamin. The resulting deficiency is more common in the elderly and institutionalized that may have restricted diets or inadequate exposure to sunlight. Phenytoin may also produce abnormalities in the roots of teeth of varying sorts.

Immunosuppressant drugs are known to affect the periodontium. Since immunosuppressants may alter the way periodontal tissue react to plaque and affect the progression of periodontal disease, much research has been done on this topic. Not all immunosuppressants have a beneficial effect as mentioned earlier with regard to azathioprine and prednisone. Cyclosporin-A (Sandimmune), a fungal fermentation product, is a powerful new immunosuppressant. It has found widespread post-operative use in renal, bone marrow and other transplant procedures. Gingival hyperplasia is now recognized as an unwanted effect of this drug (Tyldesley 1984). It occurs in about 30% of patients receiving cyclosporin. This hyperplasia appears similar clinically and histopathologically to phenytoin induced hyperplasia. Exactly how this hyperplasia is induced is not known and it appears that there may be no correlation between the severity of the hyperplasia and the patient's plaque index. Even patients with immaculate dental hygiene may still develop this unsightly problem. Hyperplasia may occur more often when serum levels exceed 400 ng/ml (Seymour 1988). The onset of the problem is rapid. Most likely this hyperplasia is due to a metabolite of the drug. Possibly cyclosporin and phenytoin share some common metabolite even though the parent structures are quite different.

One other drug that is reported to cause gingival hyperplasia is nifedipine (Procardia, Adalat), a calcium channel blocking agent (Yochanan et al 1984, van der Wall et al 1985). This drug is used widely for treatment of angina and hypertension. Gingival hyperplasia due to nifedipine use appears similar to phenytoin induced hyperplasia. The mechanism by which nifedipine causes this condition is not known. One theory that links these two drugs and possibly provide insight to the mechanism of hyperplasia is that both drugs effect calcium ion influx in nerves or muscles. However, other drugs known to affect calcium ion influx such as verapamil

are not associated with gingival hyperplasia (Seymour 1988).

Gingival hyperplasia caused by a pharmacologic agent is usually treated with gingivectomy, withdrawal of the drug and rigorous dental care and hygiene.

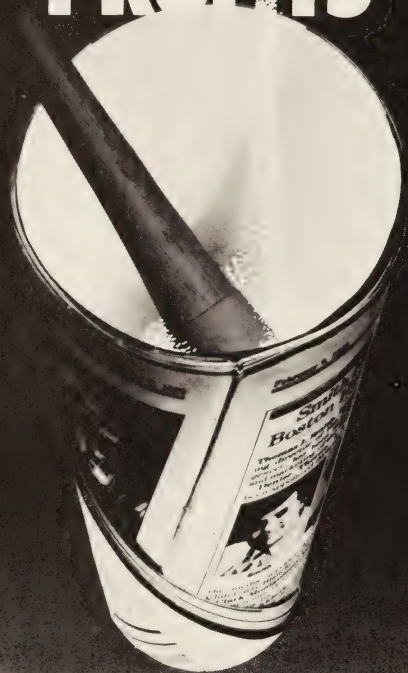
Other drugs such as sex hormones and chemotherapeutic agents affect the periodontium. Oral contraceptives are associated with gingival inflammation. It is known that estrogen and progesterone are important to maintaining normal epithelia. Post menopausal women may have altered tissue features in the mouth as result of an imbalance of these hormones. Chemotherapeutic agents causing thrombocytopenia may result in gingival hemorrhage in some patients (Seymour).



The drugs discussed above, phenytoin, cyclosporin, nifedipine, anti-neoplastics and sex hormones all adversely affect the oral health of patients receiving them. Of course the population of patients receiving these are not all elderly and these untoward effects may be seen in any age group. These problems may become severe or go unnoticed in an elderly patient without good dental care or hygiene. Elderly people may not themselves realize these changes so it is up to health professionals and caretakers to examine elderly patients on these drugs for any sign of a drug induced problem.

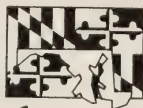
One other very common adverse side effect associated with many medications is xerostomia. Saliva is very important in monitoring oral health. As mentioned earlier, saliva serves to protect the mouth and its fixtures from damage. Without adequate saliva, chewing, swallowing, speaking and sleeping may become difficult. Clearly in an elderly patient, these effects may be detrimental to the patients well being if they are left undetected or untreated. Dental caries, dry mouth,

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burning sensations and infection also result from hyposalivation. Nutritional sequelae of hyposalivation and xerostomia are especially important in the elderly population since many elderly are nutritionally compromised for various reasons.

Causes of hyposalivation are as varied as are the results. Causes may include systemic diseases, such as diabetes, psychological disease, such as depression, infections, dehydration menopause and diseases directly affecting the salivary glands, such as obstruction, irradiation and Sjogren's syndrome. Therapeutic drugs alter normal salivation through changes in electrolyte balance and post-ganglionic transmission. It is estimated that over 200 drugs on the market in Canada may cause xerostomia (Grad et al 1985). Undoubtedly, the figure is similar in the United States. These drugs can be grouped by pharmacologic classes and include; anti-neoplastics, anti-spasmodics, anti-depressants, anti-psychotics, skeletal muscle relaxants, anti-Parkinson's agents, anti-arrhythmics, anti-histamines, appetite suppressants, anti-convulsants, anxiolytics, anti-hypertensives, diuretics, H₂-blockers and others. The first five categories listed as well as clonidine, disopyramide and isotretinoin may have a major effect on salivation compared to the others listed (Grad et al 1985).

These drugs may be very important to the health of a patient and in many cases cannot be withdrawn even in the face of severe xerostomia. Xerostomia should be recognized as an abnormal problem and treated using a combination of artificial salivas, mouth rinses and fluoride and remineralization programs.

The elderly population are, for many reasons, at risk of having untreated oral health problems. Much of the elderly population do not regularly see a dentist. There is a widely accepted belief among this group that if they become edentulous or simply grow old, they no longer need to visit a dentist (MacEntee et al 1988). Economic factors and physical access to care also prevent the elderly from receiving dental care (Drummond 1988).

As the elderly population grows to represent a larger segment of the overall population, and dental practices recognize the need to find more patients to remain financially successful, the trend may be for practitioners to seek out elderly patients more aggressively and address their needs. Better reimbursements from insurance companies and public health insurance and the use of portable dental equipment to visit patients at home or in nursing homes provide hope that the dental care needs of the elderly will be better met in the future (Giangregio 1987). Until this becomes a reality, however, it is very important that the oral health status of the elderly not be neglected. Nurses, care takers and physicians need to learn how to look for oral health problems and how to counsel a patient about their oral health condition. Health providers need to recognize what to expect as normal in the elderly and what is abnormal. They also need to become familiar

with the possible causes, consequences and treatment of these problems. Pharmacists, given the large incidence of problems caused by therapeutic drugs and the number of elderly taking them, can play an important role in educating patients and care providers of these problems. Pharmacists may also help assure that symptoms of altered oral health seen in the elderly are properly diagnosed and treated.

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Editor's Note: This article is the second of several columns featuring student research projects for the UMAB School of Pharmacy's Geriatric Imperative Course. These articles have been selected by an expert panel of reviewers including Peter P. Lamy, Ph.D., Kathleen Gondek, M.S., and Ilene Zuckerman, Pharm.D. of the School.

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NARD Resolutions Address Key Practice Issues

Nine resolutions were passed by delegates at the 92nd Annual Convention of NARD, the national association representing independent retail pharmacy. The resolutions addressed several issues, including mandatory patient counseling, nonpharmacist personnel, mail order pharmacy, equal access to fair prescription drug prices, and consumer pharmacy selection rights. The NARD convention was held October 21–25 in Nashville, Tennessee.

The convention resolutions, passed by the NARD House of Delegates on the final day of the convention, solidify the association's policies and actions on key issues affecting the professional and proprietary interests of the nation's independent retail pharmacists, as well as important issues of public health and safety.

The following resolutions were passed by this year's NARD House of Delegates.

NARD 1990 Convention Resolutions

Resolution #1

RESOLVED that the delegates of the NARD Convention assembled on October 25, 1990, in Nashville, Tennessee, ratify and confirm all official actions of the Officers and members of the Executive Committee of NARD during the interim since the last convention of NARD in San Antonio, Texas.

Resolution #2

Counseling: The Professional's Prerogative

WHEREAS, counseling and individualized personal service have been the hallmarks of independent pharmacy for decades; and

WHEREAS, some marketing practices have minimized pharmacists' counseling opportunities, such as prescription to OTC switches and indiscriminate distribution on the theory that a label can substitute for a pharmacist; and

WHEREAS, the public is easily confused by corporate advertisements featuring the concept of pharmacists counseling when in reality counseling may not be available;

BE IT RESOLVED that NARD reaffirm its support for mandatory counseling consistent with the profes-

sional judgment of the pharmacist as recently reflected in the counseling provisions of Senator Pryor's legislation, S.2605 and S.3029.

Resolution #3

Nonpharmacist Personnel Regulations and Laws Are Premature

WHEREAS, the National Association Boards of Pharmacy (NABP) is in the process of updating its model Pharmacy Practice Act; and

WHEREAS, a key aspect of the NABP review is the development of a contemporary definition of pharmacy practice; and

WHEREAS, pharmacists in select settings, including hospitals and mail order distribution centers, are urging that nonpharmacist personnel be delegated extensive responsibility in regulation and law; and

WHEREAS, it would be premature to finalize the definition of the role of nonpharmacist personnel prior to completion of the definition of the practice of pharmacy;

BE IT RESOLVED that NARD oppose any further formal expansion of the role of nonpharmacist personnel until the NABP definition of pharmacy practice is finalized and investigations of drug-related fatalities in hospitals involving the use of nonpharmacist personnel in the private sector and Medicaid and Medicare funded facilities are concluded.

Resolution #4

Alleged DEA Lawlessness

WHEREAS, 20 years has elapsed since the enactment of the Federal Controlled Substance Act (CSA); and

WHEREAS, the last congressional review of pharmacy and the CSA was in 1974, including ways to trace allegedly inappropriate CSA prescriptions; and

WHEREAS, NARD has received an increasing number of complaints and information alleging that the Drug Enforcement Administration (DEA) has abused and harassed pharmacists via misrepresentations or violations of the CSA;

BE IT RESOLVED that NARD urge the appropriate congressional committees to conduct oversight hearings into these allegations and subsequently to develop regulatory and legislative changes to help ensure that DEA is acting in a manner consistent with appropriate federal objectives and with the lawful practice of pharmacy.

Resolution #5
Medco's Twilight Zone

WHEREAS, corporations employing pharmacists who practice pharmacy via the mail are virtually unregulated or in a "twilight zone," leaving the public in the states where the prescriptions are received unprotected; and

WHEREAS, the practice of pharmacy is a profession and cannot be regulated under the Commerce Clause as commodities moving in commerce; and

WHEREAS, in the recent Iris Hemmelman death, featured by CBS, Medco Containment Services, Inc. and its subsidiaries claimed that only New Jersey, the location of its corporate headquarters, had jurisdiction over the conduct of the pharmacists, *not* Idaho, where the prescription was received, *not* Washington, where the third-party contract originated, and *not* Nevada, where the subsidiary formulated the prescription; and

WHEREAS, during the investigation of the Idaho case, law enforcement authorities determined that more than 200 similar cases existed but had not been investigated, including more than 100 that were "lost" by Medco at its corporate headquarters; and

WHEREAS, similar and comparable allegations from every corner of the country are being made against Medco, including a recent exposé by the Texas legislature:

BE IT RESOLVED that NARD request appropriate authorities in the state of New Jersey, including the Governor, Attorney General, and the Board of Pharmacy, to investigate the practice of pharmacy via the mail by pharmacists employed by Medco in New Jersey and other states, including Florida, Ohio, Texas, Nevada, and Washington; and

BE IT FURTHER RESOLVED that if it is claimed that resources are not available to conduct a thorough investigation, that NARD seek the assistance of the United States Department of Justice and the assistance of the House and Senate Appropriations Subcommittees with responsibility for the Justice Department, including the DEA and the Criminal and Organized Crime Divisions.

Resolution #6
An Honest Retail Pharmacy Census

WHEREAS, the actual number of independent pharmacies is frequently misrepresented in current reports by arbitrary distinctions, for example, including ownership of "four or more" pharmacies as a chain; and

WHEREAS, such reports are often used in an uncritical way by the press, resulting in gross mischaracterization of the actual strength of independents in the marketplace; and

WHEREAS, some interests in the marketplace have encouraged the use of such inaccurate distinctions:

BE IT RESOLVED that, on an interim basis, NARD encourage all those generating such reports to use the delineation of chain ownership as eleven or more stores, which is currently the Commerce Department criterion for a retail chain; and

BE IT FURTHER RESOLVED that for the long term NARD develop a definition that is consistent with the realities of the retail pharmacy marketplace, highlighting the importance of independent pharmacy ownership and control.

Resolution #7
Equal Access: Is Collaboration Possible?

WHEREAS, in 1985 NARD urged the pharmaceutical industry to voluntarily provide equal access to prices, and later the industry responded that only legislation would achieve the goal; and

WHEREAS, multitier pricing with its discounts for mail order, HMOs, hospitals, and nursing home phar-

macies is the source of most of independent pharmacy's problems; and

WHEREAS, even when independent pharmacies legally combined in buying groups or cooperatives, manufacturers of branded drugs refused to sell to them; and

WHEREAS, the United States Supreme Court in *Hasbrouck v. Texaco* challenged even functional discounts in that a wholesaler must demonstrate what it is actually doing to earn its discounts; and

WHEREAS, the United States Congress and the Bush Administration supported equal access for Medicaid to the nonprofit legitimate class of trade; and

WHEREAS, recent congressional consideration of equal access has been marked by acrimony and extremely derogatory comments about pharmacy and pharmacists:

BE IT RESOLVED that NARD urge the pharmaceutical industry to avoid a similar "battle royal" over equal access generally and to voluntarily take steps to assure equal access to the same prices on the same terms; and

BE IT FURTHER RESOLVED that NARD join with industry, legislators, and others in the establishment of a commission/forum to explore all voluntary and legislative alternatives to assure that independent pharmacy and its consumers, representing 70 percent of the prescription drug marketplace, are no longer denied equal access to fair prices.

Resolution #8

Enactment of Medicaid Equal Access Legislation

WHEREAS, the chairman of the Senate Aging Committee has educated Congress, the national media, and the public about the negative impact of multitier pricing on American consumers; and

WHEREAS, the chairman of the Senate Aging Committee undertook an extraordinary effort to begin to pay pharmacy restitution for the confiscation of

earned discounts since 1985, and to establish a moratorium on action by HCFA until enactment of reimbursement reform, including NARD's marketplace pricing standard; and

WHEREAS, the chairman of the Senate Aging Committee withstood a most vicious, political, and personal attack for his effort to help consumers and pharmacists:

BE IT RESOLVED that NARD especially recognize the unprecedented bipartisan effort by Senator David Pryor of Arkansas on behalf of independent pharmacy in the United States; and

BE IT FURTHER RESOLVED that NARD recognize the authors of the companion equal access bill in the House of Representatives, Rep. Ron Wyden of Oregon and Rep. Jim Cooper of Tennessee.

Resolution #9

Consumer Pharmacy Selection Rights

WHEREAS, certain health insurers in Massachusetts, including both traditional insurers and health maintenance organizations, will adopt a mail order prescription drug plan and exclusive pharmacy provider contract, respectively; and

WHEREAS, mail order prescription drug plans represent a serious threat to public health; and

WHEREAS, mail order prescription drug plans do not allow face-to-face patient consultation, comprehensive monitoring of prescription or nonprescription drug use, or access to pharmacists for emergency needs; and

WHEREAS, exclusive pharmacy provider contracts eliminate patients' freedom to use the pharmacy of their choice; and

WHEREAS, exclusive pharmacy provider contracts represent a reduction in service to the patient:

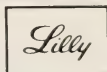
BE IT RESOLVED that NARD support legislative and regulatory action taken federally and by individual states that would ensure professional and consumer protection standards.

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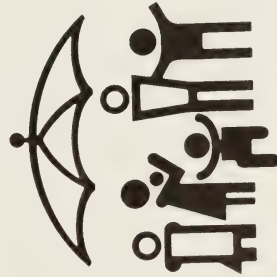


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- Pneumococcal vaccine saves lives
- Pneumococcal vaccine should provide protection for at least 5 years.

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EPIDEMIOLOGY AND DISEASE CONTROL PROGRAM

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EPIDEMIOLOGY AND DISEASE CONTROL PROGRAM

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Persons who are at high risk of pneumonia and who should receive the vaccine are: (1) persons who are 65 years of age or older, (2) persons with chronic diseases or conditions, such as heart disease, lung disease, diabetes mellitus, (3) persons who are immunocompromised, for example, Hodgkins disease, kidney failure, organ transplantation. Persons who believe they have a chronic or immunocompromising condition should consult with their doctor to see if this immunization is recommended.

If you or a member of your household is in a group for which immunization is recommended, call your doctor to arrange it. Your doctor may wish to refer you to an immunization clinic at your local health department. Contact your local health department for the location and times of clinics in your area.

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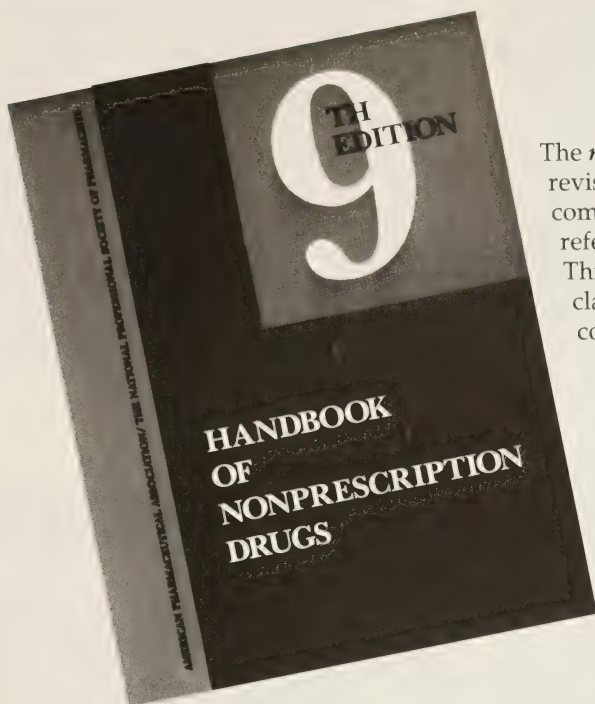


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The Maryland Pharmacists Association 1991 Mid-Year Seminar

February 10, 1991
Loews Annapolis Hotel Annapolis, Maryland

Program

- 8:00 am Continental Breakfast
Registration
- 8:45 am Presidential Welcome
Mark Levi, P.D.
- 9:00 am Continuing Education Seminar
"New Drug Update for 1991"
presented by:
Daniel Hussar, Ph.D.
- 12:30 pm Luncheon
MPhA House of Delegates Meeting
Murhl Flowers, P.D., presiding
- 2:00 pm Continuing Education Seminar
"Prescription for Temperament"
presented by: Rose Cogan, Ed.D.
- 4:00 pm Wine & Cheese Reception

Registration

Registration is \$40 for MPhA members, (\$45 for non-members) if received before January 27, 1990. Registration received after January 27, 1990 and on-site will be \$45 for MPhA members (\$55 for non-members).

To register for the Mid-Year Educational Seminar complete and detach the accompanying registration form. Return the form with payment (check or money order) to the MPhA office. For further information or questions, contact MPhA at (301) 727-0746 or (800) 833-7587.

Directions

The Loews Annapolis Hotel is located at 126 West Street in Annapolis. Lot and valet parking is available behind the hotel. From Baltimore: From I-695, take I-97 south to the merge onto Route 50 east. From Washington: From I-95, take Route 50 east to Annapolis to the Route 70/Rowe Boulevard exit. Take the Route 70/Rowe Boulevard exit into Annapolis. Route 70 will lead into Church Circle. Take the first right off of Church Circle to West Street. The Loews Annapolis Hotel is two blocks north of the Circle on the left hand side. A map is available from the MPhA office.

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February 10, 1991
Loews Annapolis, Annapolis

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MPhA staff celebrated a new arrival for DUR Secretary Davida Jones in December. David Matthew, weighing in at 6 pounds 13 ounces was born on December 11, 1990.



Pharm-PAC Treasurer Arnold Davidov presented a \$250 check from the APHA-PAC to Congressman Benjamin Cardin of Maryland's 3rd District on November 21 at Cardin's Baltimore office.



Roxane Laboratories' Saliva Substitute is now available in "pocket-able" single-dose vials, each containing 5mls. Saliva Substitute is an OTC product that is dye free, salt free, and accepted by the American Dental Association.



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Continuing Education Quiz

The Maryland Pharmacist

JANUARY 1991

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by May 1, 1991. A continuing education certificate for one contact credit will be mailed to you within 30 days. Please type or print clearly.

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Is this program used to meet your mandatory CE? ☐ Yes ☐ No

Did this article achieve its stated objectives? ☐ Yes ☐ No

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New Drugs: Part II

1. The new drug that is categorized as a nonsteroidal anti-inflammatory (NSAID) agent is:
 - a. Anafranil.
 - b. Clozaril.
 - c. Toradol.
 - d. Wellbutrin.
2. All of the following drugs are indicated for adjunctive therapy with levodopa/carbidopa in treatment of Parkinsonism EXCEPT:
 - a. Eldepryl.
 - b. Parlodel.
 - c. Parnate.
 - d. Permax.
3. Which of the drugs referred to in question #2 above acts by inhibition of MAO-B?
 - a. Eldepryl
 - b. Parlodel
 - c. Parnate.
 - d. Permax
4. Which of the following adverse effects represents the greatest concern common to use of bupropion, clomipramine and clozapine?
 - a. Agranulocytosis
 - b. Loss of libido
 - c. Parkinson-like effects
 - d. Seizures
5. All of the following are categorized as analgesics with mixed agonist and antagonist effects EXCEPT:
 - a. butorphanol.
 - b. dezocine.
 - c. nalbuphine.
 - d. propoxyphene.
6. The drug approved for treatment of patients with schizophrenia unresponsive to conventional therapy is:
 - a. Anafranil.
 - b. Clozaril.
 - c. Toradol.
 - d. Wellbutrin.
7. Of the following, the property of propofol that reportedly will be its greatest marketing tool when compared to other general anesthetics is its:
 - a. reduced pain at the site of injection.
 - b. slower onset of action.
 - c. lower order of hypotension.
 - d. more prompt recovery from anesthesia.
8. The symptoms experienced by patients with Parkinsonism are believed to be caused by an insufficient amount of which of the following neurotransmitters in the CNS?
 - a. Acetylcholine
 - b. Dopamine
 - c. Endorphins
 - d. Serotonin
9. The drug approved for treatment of obsessive-compulsive disorders is:
 - a. Anafranil
 - b. Clozaril
 - c. Toradol
 - d. Wellbutrin
10. Ketorolac exerts each of the following actions EXCEPT:
 - a. inhibition of cyclooxygenase.
 - b. inhibition of opioid receptors.
 - c. inhibition of prostaglandin synthesis.

Classified

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"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Horn and Horn Smorgasboard on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (301) 358-7036.

FREE CLASSIFIEDS. MPhA members may place a classified ad at no cost in the journal. Send your typewritten ad to 650 West Lombard St., Baltimore, Maryland 21201.

EVERY SUNDAY MORNING at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the pharmacy public relations program, "Your Best Neighbor," the oldest continuous public service show in Baltimore.

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FDA HOTLINE FOR AIDS information is 800-432-AIDS.

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The Maryland Pharmacist

VOL. 67

FEBRUARY, 1991

No. 2



*MPhA's 1991 Directory
of Third-Party Programs*

THE MARYLAND PHARMACIST

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BALTIMORE MARYLAND 21201
TELEPHONE 301/727-0746



FEBRUARY, 1991

VOL. 67

NO. 2

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The Maryland Pharmacist (ISSN 0025-4347) is published monthly by the Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201. Annual Subscription — United States and foreign, \$10 a year; single copies, \$1.50. Members of the Maryland Pharmacists Association receive The Maryland Pharmacist each month as part of their annual membership dues. Entered as second class matter at Baltimore, Maryland and additional mailing offices. Postmaster: send address changes to: The Maryland Pharmacist, 650 West Lombard Street, Baltimore, Maryland 21201.

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The Third-Party Challenge to Pharmacy

Included in this month's *Maryland Pharmacist* is our annual third-party directory with the most comprehensive data on processors' and insurance companies' prescription benefit programs. I hope that you will use the enclosed charts to help you understand the maze of rules and regulations as well as making an educated decision about which plans you will or will not accept. This is a decision you must make—the Association cannot make it for you.

When the first prescription cards were issued in the mid-1960's, their advent was hailed by the profession as a "savior" for the price pressures most consumers feel. It has only been recently that we now realize that these same price pressures are being felt by insurance companies that have been forced to reduce reimbursement in order to remain competitive.

It is up to each of us to show third-parties that we are professionals who give great value, not just a bottle of pills. Unless our patients realize this and tell their insurers or benefits managers, they will be content with mail-order and restricted access programs. It's easy to understand how a patient can think, "Who cares where the medicine comes from? The pharmacist never talks to me anyhow!"

It is up to our profession to convince HMOs and insurers that we have the expertise to make medication even more cost effective by trying to prevent adverse reactions before they become clinically important. It is up to us to demonstrate novel ideas for copayments and deductibles that may help deter utilization of a prescription benefit program.

We must create the silver lining in our clouds. Take a minute to talk with *each* of your patients who use mail-order or who can't bring all their prescriptions to your pharmacy. Ask them to add their voices to pharmacy's.

Mark A. Levi, P.D.

President

Post Script Each *Maryland Pharmacist* reader should know that the contents of this 1991 Third-Party Directory is the direct result of more than three months volunteer work by our Publications Committee Chairman Mel Rubin. Thanks, Mel!

Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

New Drugs, Part III: Cardiovascular and Miscellaneous Drugs

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

We are pleased to announce that Searle is the new sponsor of our Continuing Education for Pharmacists articles. These articles are published in state pharmacy journals around the country so thousands of pharmacists can benefit from quality correspondence pharmaceutical education. We thank Searle for their support.

Goals

The goals of this lesson are to identify and discuss new drugs approved by FDA and/or marketed during late 1989 and 1990.

A professional development
program made possible by an
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Gossel



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Objectives

At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge of the drugs discussed by pharmacologic and therapeutic classification;
2. choose the indications, mechanism of action, benefits and limitations of the drugs discussed;
3. identify adverse effects and drug interactions associated with the drugs; and
4. demonstrate an ability to counsel patients on these new drugs.

Antiarrhythmics

A brief explanation is in order to prevent confusion between the FDA rating system ("1C"), and the antiarrhythmic classification ("IC"). The former system was explained in Part I of this series, and refers to the chemical nature and potential therapeutic impact of a drug. The antiarrhythmic classification (Table 1) defines its pharmacodynamic actions on the heart.

Indecainide (1C; Decabid)

This drug is similar therapeutically to other IC antiarrhythmics: encainide (Enkaid), flecainide (Tambocor) and propafenone (Rythmol).

Although their exact mechanism is unknown, IC antiarrhythmics block passage of sodium across myocardial cell membranes. This reduces muscular contractions with the net result that IC antiarrhythmics suppress premature ventricular contraction complexes (PVCs) and depress conduction of impulses between myocardial cells. They significantly increase intraventricular conduction time without exerting significant effect on atrial or ventricular refractoriness. They do not affect cardiac output or blood pressure.

Indecainide is as effective as other IC antiarrhythmics for treating life-threatening ventricular arrhythmias. The recommended dosage is 100 to 200 mg per day. At press-time, Decabid was not marketed.

Propafenone (1C; Rythmol)

Like indecanide, propafenone is a sodium-channel blocker, with structural similarities to other IC antiarrhythmic drugs and also propranolol. The drug increases the PR and QRS interval on EKG readings, actions characteristic of IC agents. It also prolongs refractoriness in the atria and ventricles, but to lesser extent. Propafenone exerts slight (1/50th) beta-adrenergic blocking action similar to low doses of propranolol, but whether this action helps suppress

TABLE 1

Antiarrhythmic Drug Classification*

Group 1A:	Disopyramide, Procainamide, Quinidine
Group 1B:	Lidocaine, Mexiletine, Phenytoin, Tocainide
Group 1C:	Encainide, Flecainide, Indecainide, Propafenone
Group II:	Beta-adrenergic blockers
Group III:	Amiodarone, Bretylium
Group IV:	Calcium channel blockers

*Moricizine and adenosine are not classified.

the proarrhythmic effect is not certain. "Proarrhythmic" means that, since the drug alters ionic transport across myocardial fibers, it can actually cause arrhythmias.

Propafenone is indicated for treatment of documented, life-threatening ventricular arrhythmias, such as sustained ventricular tachycardia. This restrictive indication came about when, early in 1989, two other IC antiarrhythmics (encainide and flecainide) were shown to have mortality rates approximately 2.5 times greater than placebo in post-myocardial infarction patients with asymptomatic or mildly symptomatic arrhythmias. In that study (the Cardiac Arrhythmia Suppression Trial — CAST) mortality with encainide or flecainide was 56/730, versus 22/725 for placebo. There is no evidence that indecainide or propafenone have similar toxicity. Nonetheless, they are required to contain the same restrictive labeling.

Adverse effects are mild. Most common are dizziness, nausea and vomiting, unusual taste, constipation and fatigue.

The dose should be titrated upward beginning with 150 mg every 8 hours increasing to 300 mg every 8 hours if needed. Rythmol is available in 150 and 300 mg scored tablets.

Moricizine (1B; Ethmozine)

Structurally related to the phenothiazines, moricizine is used for treatment of documented life-threatening ventricular arrhythmias, such as sustained ventricular tachycardia. It is a Class I antiarrhythmic with properties of IA, IB and IC drugs. Moricizine is the only recently approved antiarrhythmic to receive a "1B" FDA classification, denoting a new chemical entity with modest therapeutic gain over existing therapies. Moricizine may be advantageous in that it is effective in patients with poor cardiac function. Many Class I drugs worsen heart function and promote heart failure.

Moricizine has a safety record that clearly distinguishes it from other antiarrhythmics. It is less proarrhythmic than other Class I drugs. The most common adverse effects involve the CNS, including lightheadedness, dizziness, numbness and headache.

Moricizine is dosed at 200 to 300 mg every 8 hours initially, titrated upward to the patient's maximal dose. Ethmo-

zine is available in 200, 250 and 300 mg tablets.

One point of interest is that moricizine is the first Soviet drug to be licensed in the U.S. Of further interest is that moricizine is the antiarrhythmic drug in the CAST study which was not discontinued, since there was no evidence of drug-induced death resulting from its use.

Adenosine (1B; Adenocard)

This antiarrhythmic drug is indicated for treatment of paroxysmal supraventricular tachycardia (PSVT). This is a non-threatening arrhythmia characterized by rapid onset of heart rate of 150 to 250 beats per minute. It slows conduction and interrupts re-entry pathways through the AV node.

Adenosine's antiarrhythmic effects appear to be due to increase in potassium conductance across cellular membranes, depression of calcium-mediated slow channel conduction and possibly, antagonism of catecholamine-mediated effects. Adenosine blocks the AV node which is thought to terminate supraventricular tachyarrhythmias and restore normal sinus rhythm. Its half-life is 10 seconds.

Adverse reactions include facial flushing, shortness of breath, headache, lightheadedness and pressure in the chest. Bronchoconstriction may be felt in some asthmatics. Overall, adenosine is remarkably safe, probably due to its short half-life and fact that it is a nucleoside normally present in the body. It is involved in many physiologic processes, including regulation of coronary and systemic vascular tone, intracardiac conduction, lipolysis in fat cells and platelet function.

The dose is 6 mg initially as a rapid IV bolus. If the first dose does not relieve tachycardia within 1 to 2 minutes, a 12 mg dose can be given also as a rapid IV bolus. This dose can be repeated a second time if required. Adenocard is available in 6 mg/2 mL vials. It should *not* be refrigerated since the solution may crystallize.

Other Cardiovascular Drugs

Anistreplase (Eminase)

This thrombolytic (blood clot dissolving) agent is indicated in the management of acute myocardial infarction (MI) in adults, for the lysis of thrombi obstructing coronary arteries, reduction of infarct size, improvement of

ventricular function following acute MI, and reduction of mortality associated with acute MI. Results of the AIMS (Anistreplase Intervention Mortality Study) investigation of 1,258 patients showed that mortality at 30 days post-infarction was decreased 47.2 percent over placebo.

Anistreplase reportedly has several advantages over other thrombolytics such as streptokinase (Streptase) and alteplase recombinant (Activase). The new drug is injected over 2 to 5 minutes, versus one hour for streptokinase and three hours for alteplase recombinant. This means that Eminase can be administered prior to, or during, transport to an emergency care center, rather than after arrival. Drug action continues as long as 4 to 5 hours after the initial injection.

Intracerebral bleeding is the adverse reaction of greatest concern, occurring in approximately 0.5 percent of patients. This is within the range of other thrombolytic agents. Both streptokinase and alteplase recombinant have values in the 0.4 percent range.

Anistreplase, also called APSAC for anisoylated plasminogen streptokinase activator complex, is administered in a dose of 30 units either directly into the vein, or diluted in an IV infusion. Eminase vials contain 30 units of anistreplase as a lyophilized powder.

Betaxolol (3C, Kerlone)

Reports substantiate that betaxolol is effective for treatment of hypertension. Advertisements stress its long half-life, thus reducing the chance for potential loss of therapeutic control by missing a dose.

Serious adverse reactions are uncommon. As with all beta-adrenergic blockers, bradycardia, hypotension, heart failure, and atrioventricular block can occur. Fatigue and CNS depression have been reported. Special caution must be taken when giving any beta-adrenergic blocker to patients with heart failure or insulin-dependent diabetes.

The dose is 10 mg once daily and can be increased to 20 mg daily. Kerlone is available as 10 and 20 mg tablets.

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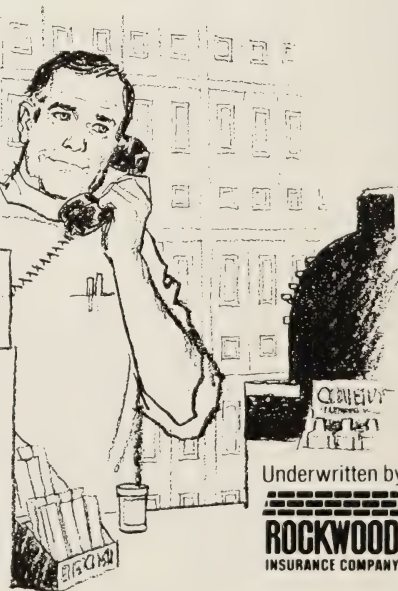
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percent in water. The perfluorochemical phase of the emulsion dissolves oxygen and carbon dioxide. When the oxygenated drug is perfused transluminally through a coronary angioplasty balloon catheter, it provides oxygen to the myocardial tissue distal to the point of balloon inflation. Repeated dosing leads to accumulation; therefore, Fluosol must not be administered more than once every 6 months.

The product is available in a 20 percent solution to be mixed to a volume of 400 mL. It is stored frozen, and warmed to 37° C prior to administration.

Pinacidil (1C; Pindac)

An arterial vasodilator, pinacidil is effective in the treatment of mild to moderate hypertension. Pinacidil is at least as effective as hydralazine, and can be used alone or in combination with a diuretic and/or beta-adrenergic blocker. Use with a diuretic is consistent with good therapeutics, since edema is reported in some patients who take the drug alone.

The drug acts primarily on arterials by direct vasodilation. At the time of writing this article, the drug had not been marketed. It appears to offer little advantage over currently available antihypertensives.

Epoetin Alfa (Epoen)

Epoetin, also referred to as recombinant human erythropoietin, EPO and rHuEPO, is a product of recombinant DNA technology. It is chemically and biologically equivalent to endogenous erythropoietin. EPO stimulates bone marrow to produce erythrocytes (red blood cells). A small amount of EPO is produced in the liver, but the bulk is synthesized and secreted by cells in the cortex and medulla of the kidney.

Human erythropoietin binds to erythroid progenitor cells in bone marrow to stimulate their differentiation into mature erythrocytes, along with other activities including increasing and maintaining erythroid progenitor cells in the proliferating pool. Its production is increased during periods of renal hypoxia caused by anemia.

There are several potential indications for recombinant EPO. The first to be approved (for epoetin alfa) is anemia associated with chronic renal failure. These patients cannot produce enough erythropoietin in their kidneys

because of excessive cellular damage. Other potential indications include anemia in AIDS patients, persons undergoing chemotherapy, rheumatoid arthritis, surgical blood loss, and renal transplants. It may also be used to increase the erythrocyte count in patients donating blood for possible use during their own surgery.

Since it is a naturally occurring hormone, there are few side effects. The most common is a rise in blood pressure. This is to be expected since more formed components are being added to the blood, raising its volume. Because most patients being treated already have hypertension, they should be closely monitored during initiation of therapy. Other reported adverse effects include seizures, flu-like symptoms and increased blood clotting.

Epoetin alfa is administered intravenously or subcutaneously to patients not on dialysis, or into the venous line at the end of a procedure for those receiving dialysis. The dosage regimen is based on the patient's hematocrit values, but the recommended starting dose is 50 to 100 units/kg three times a week. Epogen is available in vials containing 2000, 4000 and 10,000 units per 1 mL. The solution should *not* be shaken vigorously since the drug is a glycoprotein which may be denatured and rendered biologically inactive.

Other Miscellaneous New Drugs

Omeprazole (1B; Prilosec)

This is the first in a series of potent gastric acid secretion inhibitors which may eventually be marketed in the U.S. Its action exceeds that of histamine (H-2) antagonists because it acts at the final step of parietal cell secretion of acid. These cells are stimulated by a number of endogenously produced chemicals including acetylcholine, gastrin, prostaglandins and histamine. The H-2 antagonists block stimulation of acid secretion by histamine, but the other substances can still cause acid release.

The final, common step in the mechanism by which parietal cells release HCl into the stomach involves the enzyme hydrogen-potassium adenosine triphosphatase which fuels the proton pump. The net result is an exchange of hydrogen ions for potassium and secretion of acid. Omeprazole inhibits this enzyme, and is thus described as an

"acid proton pump inhibitor."

Omeprazole is rapidly degraded by low pH so it would not be effective in a regular dosage form. Instead, the drug is formulated in a delayed-release capsule that contains enteric coated granules. Patients should swallow the capsule whole on an empty stomach, preferably with a full glass of fluid.

Once the drug reaches the small intestine, it is absorbed. However, it is not active until it reaches a slightly acidic medium. Its target tissue, parietal cells, are the only cells in the body with a low pH. Therefore, omeprazole has affinity for and concentrates within them. There, omeprazole is converted to its active species and inhibits the proton pump.

When released, omeprazole was indicated only for short-term treatment (4 to 8 weeks) of gastroesophageal reflux disease (GERD), short-term treatment of symptomatic gastroesophageal reflux disease partly responsive to customary medical treatment, and long-term treatment of Zollinger-Ellison syndrome. Since then, FDA has extended its indications to treatment of acute duodenal ulcers and refractory duodenal ulcers (after H-2 receptor antagonists have been tried unsuccessfully).

A dramatic problem that occurred with the drug after its release under the trade name of Losec was that some pharmacists mistook it for Lasix and misfilled prescriptions. Compounding the problem was that both drugs were marketed in 20 mg dosage forms. Its manufacturer sent a "Dear Pharmacist" letter to warn of the potential problem. The problem continued and, in September 1990, the trade name was changed from Losec to Prilosec.

The recommended dosage of omeprazole for most of its indications is 20 mg daily. Prilosec is available as 20 mg delayed release capsules.

Metipranolol (1C; OptiPranolol)

While the exact mechanism of ophthalmic beta-adrenergic blockers has not been elucidated, it is known that they lower intraocular pressure and alleviate glaucoma. Many patients are more likely to comply with beta-adrenergic blocker therapy rather than therapy with cholinergic agents (e.g., pilocarpine) because the former do not affect accommodation and cause less blurred vision. They appear to

lower intraocular pressure by reducing production of aqueous humor and possibly increasing its outflow. The ophthalmic beta-adrenergic blockers have become agents of choice for treating open-angle glaucoma.

Although rare, optically administered beta-blockers can enter the general circulation through the lacrimal duct and cause systemic effects. This can be lessened if the patient holds a finger on and presses inward at the juncture of the upper nose and lower eyelid for a minute after administering the drops.

Side effects that have been reported include eye discomfort, blepharitis, conjunctivitis, photophobia and rarely, blurred or abnormal vision.

Botulinum Toxin (Oculinum)

This agent was approved as an orphan drug to treat adults with blepharospasm (a rare, debilitating disorder of the eye in which muscles contract, forcing the eyelid closed), and strabismus (the eye deviates away from its normal position). Botulinum toxin induces paralysis of eyelid muscles by blocking release of acetylcholine at neuromuscular junctions. It is injected subcutaneously around the eye. One treatment typically lasts up to three months and must then be repeated.

Side effects are transitory including blurred vision, irritation, and drooping of the upper eyelid. Serious reactions are rare, but may include disorientation and changes in eye alignment.

Levamisole (1A; Ergamisol)

This drug is used in combination with 5-fluorouracil (5-FU) as adjunct treatment to surgery for patients with Dukes' C stage colon cancer. This is a condition in which cancer has spread to local lymph nodes, but there is no detectable spread to other distant sites or organs. Approximately 20 percent of patients with colon cancer are candidates for the drug.

Additional studies are underway for Dukes' B stage colon cancer and rectal cancer. The drug is given in an attempt to eradicate remaining cancer cells following surgery, and thus prevent spread to other sites.

Levamisole is immunotropic in that it restores inefficient host defense mechanisms. In most animal cancer models, it does not influence growth of the primary tumor. However, it does

prolong the remission period after chemotherapy.

Toxicity includes leukopenia, agranulocytosis, severe skin rashes, fever and GI intolerance, and frequently results in discontinuance of therapy.

Levamisole's treatment regimen is 50 mg orally every 8 hours for 3 consecutive days every 2 weeks, with concomitant doses of 5-FU (450 mg/M²/day) intravenously for 5 days. The 5-FU treatment continues once a week beginning 28 days after the five-day course. Ergamisol is available as a 50 mg tablet.

Pegadamas (1A; Peg-ADA, Adagen)

This is a new drug for children with severe combined immunodeficiency disease (SCID). SCID is a rare and usually fatal genetic disorder. The drug is aimed at SCID patients with adenosine deaminase-deficiency which affects about one-third of all patients with SCID, a total of about 40 children annually worldwide. The drug replaces the enzyme, but does not prompt the body to produce the enzyme, so it does not cure the condition. Recipients must receive weekly injections for the rest of their lives. It costs approximately \$60,000 annually.

Limited side effects have been reported. These include headache and pain at the site of injection.

Colfosceril (Exosurf Pediatric) and Surfactant TA/Beractant (Survanta)

These are lung surfactants approved for use in prevention and treatment of the respiratory distress syndrome (RDS) in premature infants. RDS, also called hyaline membrane disease, affects up to 50,000 of the 250,000 infants born prematurely each year in the U.S. It is a leading cause of death and disability among premature infants.

The immature lungs of affected infants are unable to produce the naturally occurring surfactant. This foamy substance normally coats the inside of the lungs and keeps them from collapsing during exhalation.

These two products are chemically different. Exosurf is synthetic; Survanta is derived from minced cow lungs. They are instilled through a tube into the lungs after birth. Infants must be ventilated mechanically while the drug is given.

In studies so far, both surfactants have significantly reduced mortality

from RDS. Adverse effects from either drug can be managed if used properly. Apnea is reported in 40 to 70 percent, and pulmonary hemorrhage is increased two-fold with Exosurf. But infants who developed apnea had a greater survival rate and reduced incidence of severe intraventricular hemorrhage in tests with the drug. Two adverse reactions of concern with Survanta are a significant increase in intracranial hemorrhage, and increase in post-treatment sepsis.

The future looks promising for both drugs. Their use for RDS in adults has been studied. RDS occurs more often in adults than in infants — up to 60,000 each year in the U.S. The usual cause is trauma or sepsis.

Recently, three additional drugs were approved, but were not available at press-time. **Olsalazine** (Dipentum) is a form of 5-ASA, indicated for treatment of ulcerative colitis. **Idamycin** (Idarubicin) is indicated for combination therapy in acute myeloid leukemia. **Doxazocine** (Cardura) is an alpha-adrenergic blocking agent for treatment of hypertension.

Diagnostics

Iotrolan (1C; Osmovist)

Iotrolan is indicated in adults for lumbar, thoracic, cervical and total columnar myelography, and computerized tomography (CT) of spinal and subarachnoid spaces. It is only administered intrathecally.

Rubidium Rb 82 Generator (1C; Cardiogen-82)

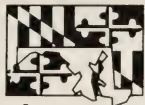
This myocardial perfusion agent is used to distinguish normal from abnormal myocardial tissue in patients with suspected myocardial infarction.

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This directory lists the addresses and phone numbers where claims are to be submitted and where contact can be made with the third-party regarding claims payment and rejections. When available, local office phone numbers are provided to expedite payment, obtain pre-authorization numbers, and plan information.

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Los Angeles, California 90010
(213) 383-1100

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(301) 621-5150—Washington, DC
(800) 962-3784

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Owings Mills, Maryland 21117
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(800) 835-3330—Eligibility

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(301) 686-2700
(800) 899-4464

CareFirst

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Utica, New York 13504
(315) 768-2409
(301) 355-3600

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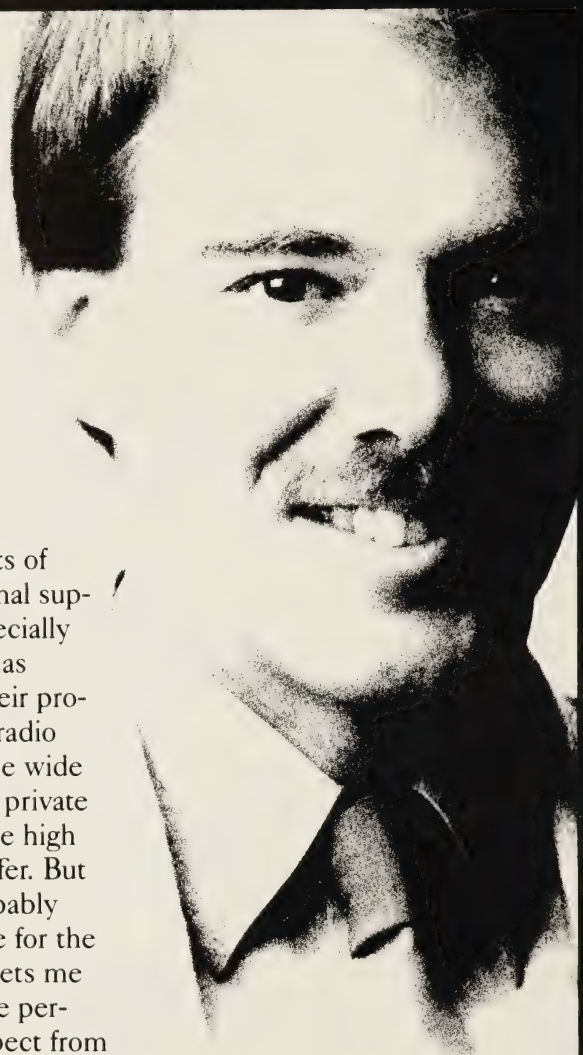
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Department of Health and Mental Hygiene
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Abuse—(301) 225-1678 or (301) 333-3020
Eligibility Verification—(800) 492-2134 in state only
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Operations—(301) 225-5349 or (301) 225-5795
Pharmacy Staff Specialist—(301) 225-1459
Preauthorization—(301) 225-1755 or (800) 492-6008
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Division of Drug Control—(301) 764-2890
State Board of Pharmacy—(301) 764-4755
Pharmacy Assistance Program—(301) 225-5392

Anorexants

No anorexants may be dispensed on a Medicaid prescription unless the physician writes in his own hand "hypokenesis" or "narcolepsy." All anorexants are affected by this rule. Ritalin (methylphenidate) is not! The following drugs are the most commonly dispensed products:

Biphetamine
Dexedrine
Obedrin
Pondimin
Tepanil

Bontril
Didrex
Obetrol
Presate
Desoxyn
Fastin
Phenteramine
Sanorex
Dexamyl
Notrol
Plegine
Tenuate

General Notes

Generic substitution requirements may be overridden by a prescriber if he/she specifies "brand medically necessary" or "brand necessary" and a diagnosis or explanation in his/her own handwriting on each prescription. Analeptics marked "BMN" do not have to have a diagnosis noted by the prescriber. The pharmacist must place an "X" in the block in the lower left corner of the claim.

All "brand medically necessary" prescriptions must be submitted on hard-copy to Medicaid. No tape billing is allowed!

You must bill the State the same price you charge a cash customer before any special discounts. You will be paid the lessor of that amount or the cost as defined by the State plus the professional fee.

If the U&C charge for a single prescription is greater than \$100 or if a single prescription is greater than \$400 and in excess of a 34 day supply, you must call for preauthorization. You may request the right to reduce the quantity. For preauthorization, call (301) 225-1755 or (800) 492-6008.

Reimbursable OTC Products

- 1) Insulin
- 2) Enteric Coated Aspirin for arthritis
- 3) Oral Ferrous Sulfate—specific quantities and dosage forms
- 4) Vaporizers, humidifiers—under separate Supply program
- 5) Syringes—under separate Supply program

Specially Assigned Medicaid NDC Numbers

Compounded prescriptions	00998-0000-00
Disposable V-100 1ml insulin syringe	00996-2222-00
Disposable V-100 (lo-dose) 0.5ml syringe	00996-2222-00
All other hypodermics/syringes	00996-1111-00
Legend drugs without NDC codes	00999-0000-00
Enteral nutrition	00999-1111-00
Non-lubricated condoms	00997-1111-00
Lubricated condoms	00997-2222-00
Home IV therapies:	
Total parenteral nutrition	00998-1111-00
Antibiotic therapy	00998-2222-00
Chemotherapy	00998-3333-00
Pain management therapy	00998-4444-00
Fluid replacement therapy	00998-5555-00
Hemophilia therapy	00998-6666-00
Miscellaneous parenteral therapy	00998-7777-00

If more than one order is dispensed at one time, e.g.: two compounded prescriptions, use the 00 for the final digits of the code for the first prescription, 01 for the second, etc. This will prevent rejections as duplicate invoices.

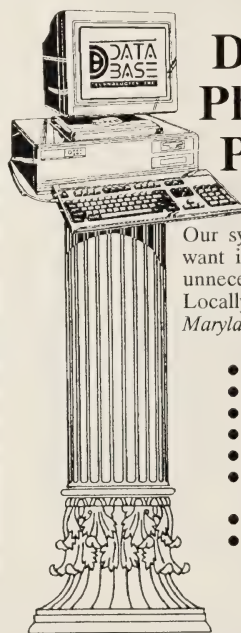
When dispensing prescriptions for chewable iron with multivitamin tablets and ferrous sulfate prescriptions, use the following NDC numbers if the product does not have its own NDC code.

Chewable iron with vitamin tablets	00997-4001-00
Ferrous sulfate drops	00997-4002-00
Ferrous sulfate elixir	00997-4003-00
Ferrous sulfate syrup	00997-4004-00
Ferrous sulfate tablets	00997-4005-00
Ferrous sulfate unit dose tablets	00997-4006-00

Rules for Condoms

Condoms may be dispensed to Medicaid recipients directly by the pharmacist. Either male or female recipients must personally present an eligible card. Twelve condoms are permitted per prescription. Only lubricated or non-lubricated latex condoms are covered—no lambskin condoms are permitted.

The pharmacist should use a refill form (DHMH 236) to write up the condom package as a prescription and the patient should sign the form where a prescriber's signature would normally go. Write the word "original" immediately below the refill block on the form. Treat each invoice as a new prescription. The patient is not required to pay any copay.



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Consult the package literature for prescribing information.
Indication: Lower respiratory infections, including pneumonia, caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Streptococcus pyogenes* (group A β -hemolytic streptococci).

Contraindication: Known allergy to cephalosporins.
Warnings: CECLOR SHOULD BE ADMINISTERED CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS-ALLERGENICITY. POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS.

Administer cautiously to allergic patients.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis.

Precautions:

- Discontinue Ceclor in the event of allergic reactions to it.
- Prolonged use may result in overgrowth of non-susceptible organisms.
- Positive direct Coombs' tests have been reported during treatment with cephalosporins.
- Ceclor should be administered with caution in the presence of markedly impaired renal function. Although dosage adjustments in moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made.
- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients.

Adverse Reactions: (percentage of patients)

Therapy-related adverse reactions are uncommon.

Those reported include:

- Hypersensitivity reactions have been reported in about 1.5% of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions have been reported with the use of Ceclor. These are characterized by findings of erythema multiforme, rashes, and other skin manifestations accompanied by arthritis/arthralgia, with or without fever, and differ from classic serum sickness in that there is infrequently associated lymphadenopathy and proteinuria, no circulating immune complexes, and no evidence to date of sequelae of the reaction. While further investigation is ongoing, serum-sickness-like reactions appear to be due to hypersensitivity and more often occur during or following a second (or subsequent) course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults with an overall occurrence ranging from 1 in 200 (0.5%) in one focused trial to 2 in 8,346 (0.024%) in overall clinical trials (with an incidence in children in clinical trials of 0.055% to 1 in 38,000 (0.003%) in spontaneous event reports. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy; occasionally these reactions have resulted in hospitalization, usually of short duration (median hospitalization = two to three days, based on postmarketing surveillance studies). In those requiring hospitalization, the symptoms have ranged from mild to severe at the time of admission with more of the severe reactions occurring in children. Antihistamines and glucocorticoids appear to enhance resolution of the signs and symptoms. No serious sequelae have been reported.
- Stevens-Johnson syndrome, toxic epidermal necrolysis,

and anaphylaxis have been reported rarely. Anaphylaxis may be more common in patients with a history of penicillin allergy.

- Gastrointestinal (mostly diarrhea): 2.5%.
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.
- As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.
- Rarely, reversible hyperactivity, nervousness, insomnia, confusion, hypertension, dizziness, and somnolence have been reported.
- Other: eosinophilia, 2%; genital pruritus or vaginitis, less than 1% and rarely, thrombocytopenia and reversible interstitial nephritis.
- Abnormalities in laboratory results of uncertain etiology:
 - Slight elevations in hepatic enzymes.
 - Transient lymphocytosis, leukopenia, and, rarely, hemolytic anemia and reversible neutropenia.
 - Rare reports of increased prothrombin time with or without clinical bleeding in patients receiving Ceclor and Coumadin concomitantly.
 - Abnormal urinalysis; elevations in BUN or serum creatinine.

- Positive direct Coombs' test.
- False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clinetest[®] tablets but not with Tes-Tape[®] (glucose enzymatic test strip, Lilly).

PA 8791 AMP (021490LRI)
Additional information available to the profession on request from Eli Lilly and Company, Indianapolis, Indiana 46285.

Eli Lilly Industries, Inc.
Carolina, Puerto Rico 00630
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Indianapolis, Indiana 46285

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Blue Cross and Blue Shield of Maryland

Mailing Address for Correspondence

10455 Mill Run Circle
Owings Mills, Maryland 21117

Mailing Address for Non-National, Non-Premium and Worcester County Account Claims

PHS
Post Office Box 80716
Los Angeles, CA 90080

Telephone Directory

BC/BS Eligibility—(301) 581-3531
or (800) 321-2398

Pharmacy Claims/Services—(301)
581-3542 or (800) 782-9986

Blue Line—(301) 581-3535 or (800)
248-8410

Pharmacy Relations/Contracts—
(301) 683-8181 or 683-8182

Fraud and Abuse—(301) 998-5480
or (800) 336-4522

Main Switchboard—(301) 581-3000
Provider Relations—(301) 581-3531
or (800) 321-2398

GM Plan Information—(301)
561-1439 or (800) 492-4209

PHS Information—(213) 391-1133
or (800) 421-2342, ext. #3

Blue Cross Generic Program

The following brand name drugs must be dispensed as generics or the patient may opt to pay the difference between the brand name price and the generic price. This list is only for non-State or non-Baltimore City employee plans.

Achromycin
Atarax
Benadryl
Diabinese
HydroDiuril
Indocin

Librium
Mycostatin
Pronestyl
Robaxinal
Tylenol/Codeine
Vistaril
Antivert
Azulfidine
Benemid
Elavil
Hygroton
Kwell
Mellaril
Orinase
Prostaphlin
Selsun
Valisone
Apresoline
Bactrim
Butisol
Enduron
Hytone
Lasix
Motrin
Procan
Robaxin
Septra
Vibramycin

Employee Group Notes

The State employee plan, designated by an "M" prefix, and the City plan, designated by a "P" prefix, use the Medicaid Interchangeable Drug List.

The State employees plan does not pay for DESI drugs or anorexants. See the general rules for Medicaid for this group. The Baltimore City employees plan does not pay for prescription vitamins and has a 150 day maintenance allowance instead of 100.

The General Motors employees plan has two different copays; if the employee is in plan "190", the copay is \$5.00. Plan "190" also has a 100 day maintenance drug list. If the employee is enrolled in a PPO, the copay is \$3.00.

General Notes

Although electronic submission of Blue Cross claims will go into ef-

fect January 1, 1991, some National account claims should still be sent to Blue Cross and Worcester County workers for processing and payment. National accounts include UAW and some others. These patients have "National" or "NASCO" imprinted on their cards. PHS will reject these claims if you try to submit them via on-line transmission.

APS Plan Format

As we add new accounts, unless there is a special feature to the Fund, there will be no bulletin sent out. If there is no plan on the I.D. card refer to the Fund Description.

A PLAN will consist of a NUMBER which defines coverage and LETTER(S) indicating the limitations and exceptions.

ALL Plans shall cover Legend Drugs UNLESS specifically excluded by the Plan.

ALL Plans shall cover cough medicines containing codeine UNLESS excluded by Plan.

ALL Plans shall EXCLUDE immunological agents and appliances UNLESS otherwise stated.

ALL Plans include Compounded Medications if at least one ingredient is a Federal Legend Drug in a therapeutic amount.

ANY Drug or Preparation prescribed for other than the Federally approved usage, WILL NOT be paid for, UNLESS authorized by the Fund.

LIMITATIONS AND EXCEPTIONS

- A — Up to a 100 Day Supply
- B — Up to a 34 Day Supply or 100 Doses, whichever is greater
- C — Up to a 34 Day Supply Only
- D — Up to a 34 Day Supply/100 Day Supply for Approved Maintenance Drugs
- E — Up to a 34 Day Supply or 100 Doses, whichever is greater.

Up to 100 Days for Approved Maintenance Drugs
F — ON PRESCRIPTION ONLY
 — Disposable syringes and needles—Testing products that are used to detect or monitor diabetes such as Clinistix, Test Tape, Visidex II,

Chemstrip, Glucospan, Glucagon Injection
G — GENERIC PLAN (See #9 in Policies and Procedures)
K — Diaphragm (Member or Spouse Only)
N — NO VITAMINS—whether legend or not

P — NO FERTILITY DRUGS
S — ON PRESCRIPTION ONLY
 — Disposable Insulin Syringes and Needles
W — NO DIET PILLS
Z — NO SMOKING DETECTANTS (i.e., Nicorette Gum)

Plan Number	Oral Cont.	Cert. OTC	Injectable	Insulin	Miscellaneous
1	YES	YES	YES	YES	
2	NO	NO	NO	YES	
3	YES	YES	NO	YES	
4	NO	YES	NO	YES	
5	YES	NO	NO	YES	
6	NO	NO	YES	YES	
7	YES	NO	YES	YES	
8	NO	YES	YES	YES	
9	NO	NO	NO	YES + Insulin Syringes	NO RX Vitamins

The following is a list of **MAINTENANCE DRUGS**. See Fund Description for **LIMITATIONS**. Note that these generic drugs are covered regardless of the brand name under which they are marketed. Any combination or dosage form of these drugs will also be considered **MAINTENANCE**.

Acebutolol
 Acetazolamide
 Acetohexamide
 Albuterol
 Allopurinol
 Amiloride
 Amiodarone
 Atenolol
 Bendroflumethiazide
 Benzthiazide
 Bumetanide
 Captopril
 Carbamazepine
 Cimetidine
 Chenodiol
 Chlorothiazide
 Chloropropamide
 Chlorthalidone
 Cholestipol
 Cholestyramine
 Clofibrate
 Clonidine
 Colchicine
 Colchicine w/Probenecid
 Conjugated Estrogens
 Cromolyn
 Cycandelate
 Cyclothiazide
 Digitoxin

Digoxin
 Diltiazem
 Dipyridamole
 Disopyramide
 Enalapril
 Encainide HCL
 Flecainide
 Furosemide
 Gemfibrozil
 Glipizide
 Glyburide
 Guanabenz
 Guanadrel
 Guanfacine
 Hydralazine
 Hydrochlorothiazide
 Hydroflumethiazide
 Indapamide
 Insulin
 Isoniazid
 Isoproterenol
 Isosorbide
 Labetalol
 Levothyroxine
 Liothyronine
 Lisinopril
 Lovastatin
 Metaproterenol
 Methyclothiazide
 Methyl dopa
 Metolazone
 Metoprolol
 Mexiletine
 Nadolol
 Nifedipine
 Nitroglycerin
 Pentoxifylline
 Phenytoin
 Pindolol

Polythiazide
 Potassium
 Prazosin
 Primidone
 Probenecid
 Procainamide
 Propranolol
 Propylthiouracil
 Quinidine
 Ranitidine
 Spirinolactone
 Sucralfate
 Sulindac
 Terazosin
 Terbutaline
 Theophylline
 Thyroglobulin
 Thyroid
 Timolol
 Tocainide
 Tolazamide
 Tolbutamide
 Triamterene
 Trichlormethiazide
 Valproic Acid
 Verapamil

***FOR ALL ACCOUNTS, THE INGREDIENT COST SHOULD NOT EXCEED \$100.00 WITHOUT PRIOR AUTHORIZATION.**

****The following are additions effective 7-1-89: Carteolol, Famotidine, Nicardipine, Nizatidine, Penbutolol, Probuco.**

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HMOs/PPOs—Chart 1

Company	FreeState +	HC 2000	Chesapeake**	Kaiser***
Cost Basis	AWP	AWP	AWP	AWP
Fee	\$2.45	+ 8%	\$2.75	\$3.00
Billing	UCF/tape/on-line	UCF	UCF/tape/on-line	UCF
Dependent Age	By Card	19/23	By Card	By Card
Refills Allowed	By law	6	2	By law
Generics Required	PHS Formulary PPD*	MD M.A. List	PHS Formulary PPD*	MD M.A. List
Doctor List	Yes	Yes	No	Kaiser Rx or approved MD
Pre-auth Required?	See Formulary	Ornade Seldane His-manal	\$100 except for chronic drugs	Certain Drugs
Maximum Days/Doses	Acute—34 Maintenance 34 days/100 doses	34 days	Pre-auth over 34 days/100 doses except chronics	60 days
Maintenance List	See Formulary	No	No	No
Maryland Rx's Only	Yes	Yes	Yes	Yes
Nicorette	No	No	Yes	Yes
Rogaine	No	No	No	No
Retin A	Yes	Acne only	Yes, to age 25	Acne only
Cyclosporine	Pre-auth	No	Pre-auth	Pre-auth
Retrovir	Pre-auth	Pre-auth	Pre-auth	Pre-auth
Fertility (ie: Clomid)	Yes	Pre-auth	If BC on ID card	Pre-auth
Rx Vitamins	Yes	Yes	Yes	Yes
Anorectics	Yes	Yes	No	Yes
BC Pills # of Packs	Most, 3 packs 1 copay	3 packs 3 copays Groups 250-254-No	If card says "BC" or 5500 series	Yes
Diaphragms & Devices	Some Cards	No	If BC on ID card	No
Insulin Quantity	Yes	Yes 4 vials	Yes 4 vials	Yes
Syringes	Yes	100	Yes with insulin	Yes
Diabetic Supplies	No on card	No	No, Yes if 5500 series	Yes, except lancets
Injections	No	No	No	Yes
Notes	Microfiche w/eligibility and MDs provided		5500 series plans—add any item covered by Medicaid.	

+ HealthNet FreeState follows the same rules as regular Free State patients, however, their cards look different. They say "Wilse HealthNet FreeState." FreeState requires generics on all prescriptions except for certain classes—specifically the analeptics and some cardiovasculars. Refer to the FreeState Formulary for specific information on generics.

* PPD—Patient pays difference if brand name is dispensed and a generic product is available or required by the plan.

**—Chesapeake Health Plan covers some medical supplies, no progesterone suppositories. Cards marked "BC" cover birth control pills only. Cards marked "R-BC" cover birth control pills and prescriptions. There are no copays for nursing home patients. Temporary cards cover oral contraceptives, diaphragms, fertility products and diabetic tests.

*** —Kaiser has some reduced copays for Baltimore sites. Some have 50% copays and some have \$50 deductibles. No emergency room prescriptions are permitted. Patient must pay and seek reimbursement from Kaiser directly.

HMOs/PPOs—Chart 2

Company	MD-IPA +	Johns Hopkins Health Plan	ALTA Admin.	Cigna***
Cost Basis	AWP	AWP—10%	WAC + 2.6%	AWP
Fee	varies	\$2.00	\$5.00	\$2.35
Billing	UCF/tape/on-line	UCF/tape/on-line	UCF/tape/on-line	UCF
Dependent Age	By Card	By Card	List sent to pharmacy	By Card
Refills Allowed	By law	By law	By law	1 year
Generics Required?	Strongly advised	Pt. pays for brand	State Formulary	State Formulary
Doctor List?	No	Only Hopkins Plan MDs	No	No
Pre-auth Required?	No	Some drugs	No	No
Maximum Days/Doses	>34 days or 100 units	34 days most drugs	34 days/90 day lists	<34 days or 100 units
Maintenance List	Yes	100 day limited	Yes, by therap. class	For Allied Signal
Maryland Rx's Only	Yes	Yes	Yes	Yes
Nicorette	No	Preauth.	No	No
Rogaine	No	No	No	No
Retin A	Yes	Acne only	Yes	To age 25
Cyclosporine	Yes	Yes	Yes	No
Retrovir	Yes	Preauth.	Yes	No
Fertility (ie: Clomid) (ie: Clomid)	Clomid only	Yes	Yes	Yes
Rx Vitamins	Yes	Yes	Yes	Yes
Anorectics	Yes	No	Yes	Yes
BC Pills # of Packs	3 months, 1 copay	Pre-auth	Some plans, 3 packs	Yes, except Allied Signal
Diaphragms & Devices	No	No	No	No
Insulin Quantity	Yes	1 vial	Yes, 90 days	Yes
Syringes	FIO**	FIO	FIO	No, except for Allied Signal
Diabetic Supplies	Yes	Yes	Yes, no devices	No, except for Allied Signal
Injections	Pre-auth	Pre-auth	No	No
Notes	Some \$50 deductible plans.		No dental	

+ Cards for plans called Optimum Choice, Alliance or MAPSI are all MD-IPA type plans. Follow MD-IPA rules and send them to MD-IPA.

* The Johns Hopkins Health Plan does not cover nystatin powder, progesterone suppositories, Yocon, or Hydergine. Pre-authorization is required for Mevacor, Questran, and amphetamines. Some JHHP subscribers have prescription coverage for birth-control pills only.

** FIO—syringes are allowed for insulin only

*** Compound NDC for Cigna—77777-7777-77

General Insurers—

Chart 1

Company	Aetna	APS	NPA	Medimet
Cost Basis	ACQ	AWP	AWP	GE—U/C others ACQ
Fee	\$4.00	Up to \$2.75	Lower of U/C or AWP + fee Fees vary	\$3.20
Billing	UCF/tape/on-line	UCF/tape/on-line	UCF/tape	UCF/tape
Dependent Age	19/23	Most 19/23	Most >19	GM 19/25 Most 19/25 Some no limit
Refills Allowed	1 year	By law	Some 6 months, most 1 year	1 year or By law
Generics Required?	No	See card. If generic, use State formulary	Some plans split copays*	GM—MAC unless DAW. Some—MAC CF—FDA MAC list
Doctor List	No	No	No	No
Preauth. Required	No	\$100	No	No
Maximum Days/Doses	Most 34 days Some 100	See APS chart	Greater 34 days/100 doses	GM—34 days 100/200 doses (2 lists) Most 34 days/ or 100 units
Maintenance List	100 day/doses if on list	Yes	No	Some plans 100 or 200 day lists.
Maryland Rx's Only	If list '2' on card	Yes	Yes	Yes
Notes	Send Transmittal	\$1.25 compound fee	\$1.00 compound fee	
Nicorette	Some groups	Unless Z on card	Most No	Yes
Rogaine	No	No	Most No	No CF**
Retin A	Yes	Some plans	Up to Age 19	Yes
Cyclosporine	Yes	Preauth	Preauth	Yes
Retrovir	Yes	Preauth	Most No	Yes
Fertility (ie: Clomid)	Yes	Unless P on card	Most No	GM—Yes Most—Yes
Rx Vitamins	Yes	Unless N on card	Most No	Yes
Anorectics	Yes	Unless W on card	Most No	Yes
BC Pills # of Packs	If "C" on card	3	Plans 1,3	GM—No Some groups CF—if Rx/C on card
Diaphragms & Devices	No	K on card	No	No
Insulin Quantity	34 days	Yes	1 month	CF—Yes GM—Yes Others—some
Syringes	Insulin only	Plan 9: Code S or F only	Yes	GM—Yes with insulin Others—some
Diabetic Supplies	Supplies no devices	Code F	No	No
Injections	Home use only	Some plans	Most plans	Yes

* NPA requires all generics be substituted even if they are not considered equivalent by the Maryland Formulary Committee. If a generic is required and patient requests brand, the patient must pay the difference.

** CareFirst (CF) will pay for Rogaine if the physician has obtained approval for its use as a medical necessity.

General Insurers—

Chart 2

	Blue Cross General**	State Program***	Carpenter Fund	Iron Workers Local 16
Cost Basis	ACQ	ACQ	AWP	AWP
Fee	\$3.30	\$3.00	\$2.60	\$2.50
Billing	UCF/tape/on-line	UCF/tape/on-line	UCF/tape	UCF
Dependent Age	19/23	19/23	19/23	19/23
Refills Allowed	1 year	1 year	By law	5
Generics Required?	Yes *PPD	MA List *PPD	Yes *PPD	No
Doctor List?	No	No	No	No
Preauth. Required?	No	No	\$200	No
Maximum Days/Doses	<34 days/100 doses +	34 days 150 maint +	>34 days 100 doses	>34 days or 100 doses
Maintenance List	No	Yes	90 days specified	No
Maryland Rx's Only	Yes	Yes	Yes	Yes
Nicorette	Yes	Yes	Yes	No
Rogaine	No	No	No	No
Retin A	Acne Only	Acne Only	Acne Only	Up to Age 19
Cyclosporine	Yes	Yes	Yes	Yes
Retrovir	Yes	Yes	Yes	Yes
Fertility (ie: Clomid)	Yes	Yes	Pre-auth	Yes
Rx Vitamins	Yes	No	Yes	No
Anorectics	No	No	Yes	No
BC Pills # of Packs	If "PCD" 3 months +	If "PCD" 3 months +	Yes	No
Diaphragms & Devices	No	No	No	No
Insulin Quantity	4 vials 1 copay	4 vials 1 copay	Yes	No
Syringes	No	No	Yes	No
Diabetic Supplies	No	No	No	No
Injections	Yes	Yes	No	No

* PPD—Patient pays difference when a brand name product is dispensed and a generic equivalent is available or required.

** General Motors employees have a \$5.00 copay *except* if they are members of a PPO and then the copay is \$3.00. General Motors will continue its 30 day Good Faith payments although Blue Cross will discontinue all other "Good Faith" payments with the new electronic billing through PHS. All claims should reflect a correct date of birth for the patient.

*** The Baltimore City program has a 150 day maintenance program and vitamins are not covered. Fee is \$3.30. The City pays for DESI drugs but the State does not. Most other rules are the same between the City and the State programs.

• All Blue Cross programs require 1 copay/34 days supply for items not on maintenance list. If on maintenance, 1 copay per maximum day supply is allowed.

General Insurers—

Chart 3

Company	Maryland Medicaid +	PCS	Lincoln National*	PERx
Cost Basis	EAC or IDC list	varies	AWP-5%	varies
Fee	\$3.70 or U/C	varies	\$3.45	varies
Billing	UCF/tape	UCF/tape/on-line	UCF/tape	UCF/tape
Dependent Age	Individual Card	On Card	19/23	18—Students have own card
Refills Allowed	2	1 year	5	1 year or by law
Generics Required?	Yes, see IDC list	Some plans	Yes	Recommended
Doctor List?	No	No	No	No
Pre-auth Required?	>\$400 or >\$100 for >34 days	No	No	No
Maximum Days/Doses	<34 days Some 100 day	Varies	34 days	Varies
Maintenance List	Yes	Yes	No	Yes
Maryland Rx's Only	Yes	Yes	Yes	Yes
Nicorette	Yes	RECAP**	No	varies
Rogaine	No	No	No	varies
Retin A	Yes	RECAP	Yes, to Age 25	varies
Cyclosporine	Yes	RECAP	Yes	varies
Retrovir	Yes	RECAP	Yes	varies
Fertility (ie: Clomid)	Yes	RECAP	Yes	varies
Rx Vitamins	Yes	RECAP	Yes	varies
Anorectics	No	RECAP	Yes	varies
BC Pills # of Packs	6 months supply	RECAP	Plan 1090	Some plans 1 month supply
Diaphragms & Devices	Diaphragms	No	No	varies
Insulin Quantity	Yes 100 days	RECAP	Yes	3 vials
Syringes	Yes	RECAP	No	Up to 100
Diabetic Supplies	No, use Supply Program	RECAP	No	varies
Injections	Limited to home or nursing home administration	RECAP	Epipen/Anakit only	varies
Notes	No DESI drugs	Group 34331000 has \$50 annual deduct then 20–30% copayments.		

+ Effective January 1, 1991 Medicaid Federal category recipients must pay 50 cents per prescription unless they are under 18 years old or are in a special category (eg. family planning). Medicaid State category recipients must pay \$1.25 per prescription.

* Lincoln National HMO claims are submitted through PCS but you must be a Lincoln National approved network member. All other Lincoln National plans (non-HMO) follow PCS published rules. These plans are numbers 1090, 254 and 1063. No DESI drugs are paid for, nor are products for chemical dependence (eg. Antabuse or Methadone). Lincoln National Plan 254 maximum is 34 days supply or 100 doses.

** Coverage of certain products varies by PCS plan. Refer to the RECAP response or check the individual plan sheet in the PCS reference manual.

General Insurers—

Chart 4

Company	PAID	PDI	Penn Scripts*	Tristate
Cost Basis	Many ACQ Varies	AWP	AWP	AWP
Fee	varies	\$2.75	Lower of U/C or AWP + \$2.75 to \$3.25	\$2.70
Billing	UCF/tape/on-line	UCF/tape	UCF/tape/on-line	UCF
Dependent Age	Most 19/23	19/23	OK, if name on Rx card	18, some student ex- tensions
Refills Allowed	By law	By law	By law	By law
Generics Required?	Many plans Use FDA list	Some plans. Some have split copay	Patient Copay Incen- tive	Some plans No copay if generic.
Doctor List?	No	No	No	No
Preauth. Required?	No	>\$200	No	>\$75
Maximum Days/Doses	Most 34 days. Some plans 100 units.	Greater of 34 days/100 doses	Greater of 34 days/100 doses	100 days
Maintenance List	No	No	No	No
Maryland Rx's Only	Most Plans	Yes	Yes	Yes
Nicorette	Some plans	Some plans	No	Yes
Rogaine	No	Yes	No	No
Retin A	Some plans	Acne only	Up to Age 30	No
Cyclosporine	Some plans	Pre-auth	Yes	Pre-auth
Retrovir	Some plans	Pre-auth	No	Pre-auth
Fertility (ie: Clomid)	Some plans	Pre-auth	No	Yes
Rx Vitamins	Some plans	Yes	No	Yes
Anorectics	Some plans	Yes	No	Yes
BC Pills # of Packs	Some plans	Some plans Up to 3, 1 copay/pack	Plan A—No others— Yes	Yes, but not for child.
Diaphragms & Devices & Devices	Plan 2D	No	No	No
Insulin Quantity	Except 2L and 94	3 vials	Yes, Maximum of cost + 50%	Yes
Syringes	Some plans	Up to 30 w/insulin only	Plan A—No Others— Yes	No
Diabetic Supplies	Some plans	Some plans	No	No
Injectables	Some plans	No	No	No
Notes	Provides chart with plan rules. No DESI list with some plans.		\$500/year maximum on some plans. No nursing home cov- erage.	

* Penn-Scripts did not respond to our survey. The listed information is repeated from last year's issue and may not be accurate. Please refer to plan information provided directly from Penn-Scripts.

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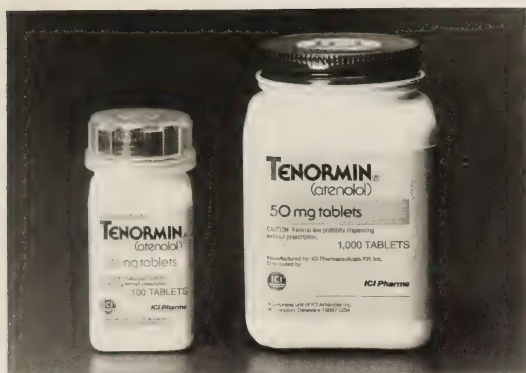


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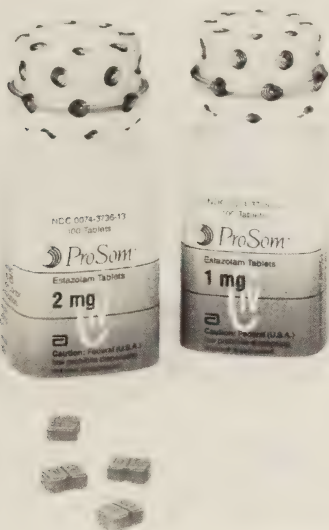
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Last year's Mid-Year Meeting was an enormous success—breaking attendance records at 353 pharmacists. Watch next month's issue for photos and highlights of the 1991 Mid-Year Meeting!

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Continuing Education Quiz

The Maryland Pharmacist

FEBRUARY 1991

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by June 1, 1991. A continuing education certificate for one contact credit will be mailed to you within 30 days. Please type or print clearly.

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New Drugs, Part III

1. Which of the following antiarrhythmics is structurally similar to propranolol and exerts mild beta-adrenergic blocking action?
 - a. Adenocard
 - b. Decabid
 - c. Ethmozine
 - d. Rythmol
2. When an antiarrhythmic drug has proarrhythmic action, it means the drug:
 - a. is indicated for arrhythmias emanating above the AV node.
 - b. is indicated for arrhythmias emanating below the AV node.
 - c. alters ionic transport across myocardial fibers and can cause arrhythmias.
 - d. alters ion transport across both atrial and myocardial fibers and therefore is indicated for all types of arrhythmias.
3. A prescription written for omeprazole 20 mg daily should be filled by dispensing:
 - a. Ergamisol.
 - b. Kerlone.
 - c. Lasix.
 - d. Prilosec.
4. The drug classed as a IC antiarrhythmic exerts all of the following effects EXCEPT:
 - a. blocking the passage of sodium across myocardial cell membranes.
 - b. lowering intraventricular conduction time.
 - c. suppressing premature ventricular contractions.
 - d. depressing conduction of impulses between myocardial cells.
5. All of the following drugs are classed as IC antiarrhythmics EXCEPT:
 - a. Adenocard.
 - b. Enkaid.
 - c. Rythmol.
 - d. Tambacor.
6. Which of the following drugs is unique in that it is the first drug developed in the Soviet Union to be licensed for sale in the U.S?
 - a. Adenocard
 - b. Decabid
 - c. Ethmozine
 - d. Rythmol
7. Which of the following is biologically equivalent to an endogenous peptide that stimulates production of red blood cells?
 - a. Adagen
 - b. Eminase
 - c. Epogen
 - d. Fluosol
8. The Cardiac Arrhythmia Suppression Trial study resulted in all of the following EXCEPT:
 - a. a higher mortality associated with encainide and flecainide than with placebo.
 - b. restriction of the indication of encainide and flecainide to documented life-threatening ventricular arrhythmias.
 - c. removal of encainide and flecainide from the market.
9. All of the following statements about moricizine are true EXCEPT:
 - a. it is chemically related to phenothiazines.
 - b. it is the only newly released antiarrhythmic to receive a "1B" classification from FDA.
 - c. it is the antiarrhythmic that was continued in the CAST study when others were discontinued.
 - d. it is more proarrhythmic than encainide and flecainide.
10. Which of the following drugs is the same as an endogenously produced nucleoside that regulates many physiologic processes?
 - a. Adenocard
 - b. Decabid
 - c. Ethmozine
 - d. Rythmol

Classified

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THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Horn and Horn Smorgasboard on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (301) 358-7036.

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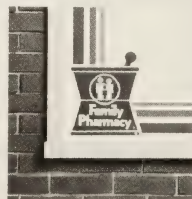
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The Maryland Pharmacist

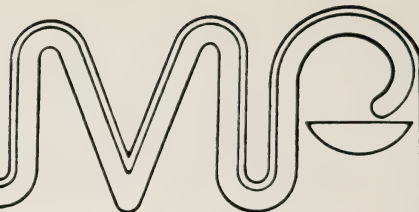
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March, 1991

No. 3



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The Maryland Pharmacist (ISSN 0025-4347) is published monthly by the Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201. Annual Subscription — United States and foreign, \$10 a year; single copies, \$1.50. Members of the Maryland Pharmacists Association receive The Maryland Pharmacist each month as part of their annual membership dues. Entered as second class matter at Baltimore, Maryland and additional mailing offices. Postmaster: send address changes to: The Maryland Pharmacist, 650 West Lombard Street, Baltimore, Maryland 21201.



Whose on First?

How many times have you said to yourself, "If we had only thought of that!"? This past month, your Board of Trustees met for the first in a series of long range planning sessions. The MPhA is actively working to face our current issues and debates but also to tray and anticipate future issues and events. I believe that with a strong strategic plan, one that says who we are and where we're headed, our organization can only be stronger.

So many issues are common to all pharmacists. Whether professional standards, patient counseling requirements, third-party and governmental interference, every practitioner has a vested interest. MPhA hopes that its strategic plan will help us meet these issues with the greatest of efficiency.

You deserve no less than your leadership's best efforts to try to predict the future and ensure that we meet that future strongly. We can't do it alone, of course. I ask any and all of you to think of what is happening now and to help us mold the future to our needs and wants. Please write or call and let us know of your ideas. After all, maybe you'll be the pharmacist we can point to and say "He thought of that first!"

Mark A. Levi, P.D.

MPhA President

P.S. Watch for the special commemorative issue of *The Maryland Pharmacist* celebrating the 150th Anniversary of the University of Maryland School of Pharmacy! Scheduled for May, this issue will feature a history of the school and highlights from celebration events.

Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION •

VOL. VII, NO. 10

Correspondence Course

Advising the Urinary Incontinent Patient

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. explain the causes and treatments of incontinence; and
2. provide specific information to convey to consumers to insure they will correctly use medication and other devices for incontinence to maximize therapy.

Objectives

At the conclusion of this lesson, participants should be able to:

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1. state the most common causes of incontinence;
2. choose from a list of drugs, those appropriate for specific types of incontinence;
3. list non-therapeutic methods to reduce the incidence and/or severity of incontinence;
4. state major pharmacologic and toxicologic considerations associated with the drugs discussed; and
5. indicate points of information to relate to patients about drug and non-drug therapy of incontinence.

Urinary incontinence is a loss of bladder control. Loss can be slight (involuntary leakage of a few drops), partial (moderate to heavy loss), or total (complete involuntary bladder emptying). Fecal incontinence is loss of bowel control. Neither are diseases *per se*. They are symptoms with numerous causes.

This lesson focuses on urinary incontinence.

Background and Incidence

It is reported that at least 10 million Americans are incontinent. The actual incidence may be much larger because it is well known that many people are too embarrassed, even humiliated, to admit their problem. Only about one in 12 afflicted persons seeks medical help. It is often referred to as the "silent symptom" or "closet disease."

Women are more often affected than men. No age is spared; 7 million known sufferers are under 65 years of age. The elderly may be more seriously affected, both physically and socially. Too often, incontinence is the major reason for institutionalization. It is said to be the fifth leading cause of admission to long-term care facilities. Nearly 50 percent of nursing home residents are incontinent.

Urinary Tract

The human urinary tract is shown in Figure 1. Urine formed in the kidneys passes through the ureters into the bladder. About 300 mL normally collects before intravesical (within the bladder) pressure becomes sufficiently great to cause the urge to void. The detrusor muscle then contracts, the internal and external sphincters relax,

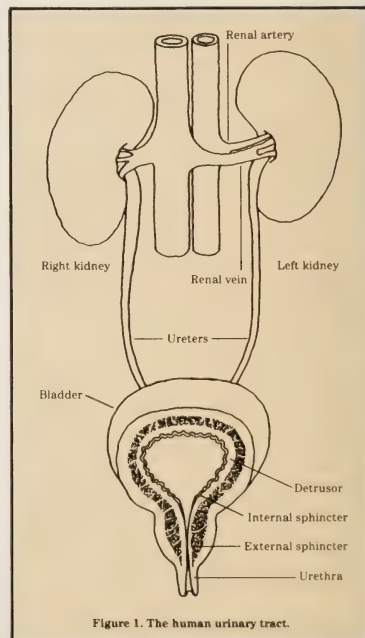


Figure 1. The human urinary tract.

and urine is expelled and drained outward through the urethra. The longer urethra of males may help account for their not being incontinent as often as females.

Autonomic Control of Bladder

Function. Bladder control is influenced by sympathetic and parasympathetic innervation. By understanding these basic mechanisms, the role of drugs that cause, and others used to treat, incontinence can be understood.

Sympathetic stimulation normally maintains sphincter constriction to inhibit voiding. Sympathetic control is mediated through both alpha- and beta-adrenergic receptors. Alpha receptors mediate the bladder outlet and urethra, and increase muscle tone. Beta-adrenergic receptors in the bladder body and dome assist in bladder relaxation. Parasympathetic receptors are spread throughout the bladder, outlet, and urethra. Their stimulation contracts the detrusor and overrides sympathetic tone, thus promoting voiding.

Intravesical Pressure. Intravesical pressure is dependent upon three forces: (1) detrusor tone, (2) volume of urine within the bladder, and (3) intra-abdominal pressure. As long as the intravesical pressure is less than pressure within the urethra, continence (bladder control) is maintained. Intraurethral pressure is governed by three forces: (1) tone of smooth muscle of the urethra and bladder neck, and periurethral striated muscle, (2) thickness of the urethral mucosa, and (3) intra-abdominal pressure. When intravesical pressure exceeds intraurethral pressure, urine will be voided.

Incontinence Classification

Incontinence can be subgrouped into five types: stress, urge, overflow, functional, and iatrogenic.

Stress Incontinence. This type accounts for up to one-half of all incontinence, being more common in women, especially of childbearing age and older. It follows events that lower intraurethral pressure below the intravesical pressure; such as coughing or sneezing, laughing, bending, or lifting clumsy or heavy objects. At this point a small amount of urine (up to 15 mL or so) can be lost.

Common causes include a shift in the ureterovesical angle, estrogen deficiency, or damaged or altered muscle tone of the external sphincter including deterioration associated with ag-

ing, multiple child birth, or surgery.

In men, stress incontinence is most often associated with urinary tract infection, chronic inflammation, or following urologic or prostate surgery or radiation therapy.

Signs that suggest stress incontinence include lack of nocturia (in contrast with urge incontinence), and loss of urine associated with coughing, straining, or laughing. Psychological or emotional tension or stress are not considered to be predisposing conditions, although some women state that anxiety or nervousness makes their condition worse.

Urge Incontinence. Identified as a sudden, uninhibited contraction of the bladder, urge incontinence is often a disease of the elderly. The entire bladder contents are emptied, often with explosive force.

Causes include CNS pathology such as intracranial tumors, cerebrovascular accident, lobotomy, multiple sclerosis, and hydrocephalus (abnormal accumulation of fluid within the cranium). Persons with Parkinson's or Alzheimer's disease also experience urge incontinence. Peripheral conditions such as uterine prolapse, neoplasm, fecal impaction, infection, inflammation, prostatic hypertrophy, or scar tissue following surgery, can also cause the problem.

An important cause of urge incontinence is "deconditioning" the voiding reflex. This can occur over time, for example, following a period of incontinence. A person may become so anxious about the threat of incontinence that he voluntarily voids often. The resulting low bladder volume gradually increases detrusor tone and thickness, which in turn, exacerbates the problem.

Signs that suggest urge incontinence include a sudden necessity to urinate, frequency, small volume, and nocturia.

Overflow (Paradoxical) Incontinence. Overflow incontinence can occur when intravesical pressure exceeds intraurethral pressure only at exceptionally high bladder volume (in contrast with urge and stress incontinence where the bladder may not be so greatly filled). This results in spilling of small amounts of urine from a full bladder. The term "paradoxical" refers to the early stages of the disorder, when it may actually be difficult to void.

Common causes include bladder

outlet obstruction, impaired sensory input, weakened detrusor muscle, enlarged prostate, multiple sclerosis, and spinal cord injury. Typically, overflow incontinence is assured when the person has suprapubic tenderness or reduced urine flow.

Functional Incontinence. This form is not actually a disorder of the bladder, but a "function" of events or factors that keep people from getting to the bathroom in time. Intravesical pressure continues to increase to the point where urine loss will be imminent.

Functionally-incontinent patients may have musculoskeletal limitations such as severe arthritis or muscle weakness, be confined to bed or a wheelchair, or may have psychological problems that prevent them from following normal toilet practice. These persons may be depressed, or angered at other persons or with their environment. Their inattention to the normal urge to void is their means to display anger, resentment, or other emotional traits.

Iatrogenic Incontinence. Drugs such as diuretics, muscle relaxants, sympathetic blockers, and many psychoactive and neuroleptic agents can cause iatrogenic incontinence. Agents such as anticholinergics and antihistamines that lead to urinary retention can cause overflow incontinence. Iatrogenic incontinence is best treated by modifying drug therapy to eliminate the offending cause.

Management of Incontinence

Thirty percent of all cases are treatable, and all are manageable. Urge and stress incontinence are the most difficult to treat. Incontinence still remains a complex problem, however.

Drugs used in management are summarized in Table 1. Urinary tract antispasmodics that are officially indicated for use in incontinence control are listed in Table 2.

Stress Incontinence. Treatment is directed toward improvement of sphincter function. Anticholinergics *per se*, or drugs with anticholinergic activity such as imipramine, and alpha-adrenergic stimulants, can achieve this goal. Beta-adrenergic blockers promote greater bladder filling. Estrogens improve alpha-adrenergic receptor sensitivity to stimulation in women. Estrogen therapy may be all that is required to manage stress incontinence in some women.

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Table 1

Drugs Used to Treat Urinary Incontinence

<i>Class</i>	<i>Action</i>	<i>Adverse Effects</i>
CHOLINERGICS Bethanechol	Increase intravesical pressure in the hypotonic bladder.	Salivation, flushing, abdominal cramps, diarrhea, sweating
ANTICHOLINERGICS Belladonna alkaloids Propantheline	Decrease activity in hypotonic bladder. Used in urge incontinence, especially in neurologic impairment.	Dry mouth, blurred vision, constipation, restlessness, euphoria, fatigue, inhibited sweating
ANTISPASMODICS Flavoxate* Oxybutynin*	Directly depress bladder smooth muscle activity; produce local anesthesia.	As above
ALPHA-ADRENERGIC STIMULANTS Ephedrine Phenylpropanolamine	Stimulate urethral sphincter resistance; sometimes effective in stress incontinence.	Epigastric distress, nervousness, palpitations, cardiac arrhythmias, insomnia
ALPHA-ADRENERGIC BLOCKERS Phenoxybenzamine	Reduce urethral sphincter resistance; occasionally used to treat overflow incontinence; may be combined with bethanechol to increase bladder pressure and decrease outlet pressure.	Orthostatic hypotension, loss of ejaculatory function, nasal congestion, miosis, tachycardia
MISCELLANEOUS		
Estrogen	Increase sensitivity to alpha stimulation.	Nausea; increased risk of endometrial cancer
Benzodiazepines	Relax detrusor and bladder sphincter; used in overflow incontinence.	Sedation, sleepiness, GI irritation, possible confusion in elderly
Imipramine	Provides alpha stimulation and anticholinergic activity.	Dry mouth and eyes, bladder obstruction in men with enlarged prostate

*Officially indicated in urinary incontinence

Use of a pessary (a device placed intravaginally to support the uterus; commonly a donut-shaped ring) by women, or surgery to restore the normal ureterovesical angle, may relieve the problem. These aid the pelvic muscles in contracting the urethral muscle, thereby increasing its resistance against intravesicular pressure and loss of urine. Men may also benefit from surgery when incontinence is caused by tumors of the bladder, or other growths within the urethral canal.

Urge Incontinence. Treatment is directed at blocking detrusor contraction. Drugs such as anticholinergics, antispasmodics, and (unofficially) calcium channel blockers may be helpful. When conditions necessitate, surgery will be performed to remove tumors, or correct a hypertrophied prostate gland or prolapsed uterus.

Urge incontinence is often reversible in younger children. While it may

likewise be reversible in older adults, it usually is not.

Overflow Incontinence. Drug therapy includes muscle relaxants such as benzodiazepines which help relax detrusor and outlet resistance. Alpha-adrenergic blockers may help decrease internal sphincter tone. Cholinergic stimulants such as bethanechol may increase intravesicular pressure and promote a more normal void pattern. These agents have limited usefulness in elderly persons, because of inherent toxicity. Surgery is therapeutic if obstruction, such as an enlarged prostate, is the cause of reduced outflow.

Intermittent self-catheterization is almost always effective. Once the technique is mastered, patients may perform this every 2 to 4 hours to release urine and prevent its back-flow into the kidneys. The primary complication of overflow incontinence is hydronephrosis (distention of the pelvis and

calices [cavities] of the kidney, with accompanying destruction). Catheterization can alleviate this.

Functional Incontinence. There is no direct drug treatment of functional incontinence. Alleviation of underlying psychological causes with appropriate medication may help. An effective way is for these persons to chart their urine voiding patterns. Once a pattern is developed, it can then be anticipated when urination is most likely, and appropriate steps can be undertaken. Absorbent undergarments, or catheterization of nonambulatory patients may also be appropriate.

Dealing With Odor. Good hygiene minimizes the chance of malodor occurring. OTC internal deodorant tablets containing chlorophyllin copper complex and bismuth subgallate are used to reduce urinary and fecal odor associated with incontinence. Examples include Nullo® and Chloresium®.

In addition to pharmacologic means of management, there are numerous other products and activities that may benefit incontinent individuals. For example, there is a wide range of **disposable undergarments, diapers, and shields** for ambulatory and nonambulatory patients. These are composed of light-weight, highly absorbent, non-allergenic materials that are comfortable to wear, and easy to dispose of. Shields of similar construction that are worn inside traditional undergarments are intended for less serious incontinence problems. There are also **reusable garments** consisting of rubber- or vinyl-lined interiors, or polyester briefs that accommodate insertable absorbent pads.

Condom-catheters and penile clamps are used by men. Condom-catheters (Texas catheters) envelope the penis just as a regular condom does. They are held in place with adhesive. These devices are longer than the flaccid penis and either have a clamp to hold back urine flow until it can be disposed of properly, or are connected to a urinary drainage bag. As an alternative, traditional condoms may work just as well if urine loss is minimal, such as with stress incontinence.

Penile (Cunningham) clamps can be uncomfortable, and potentially dangerous. If too tight, they can restrict blood flow into the penis. Left in place too long, urinary tract infection may develop.

Intermittent catheterization is an acceptable treatment for overflow incontinence. Performed aseptically, it is safer than indwelling catheterization.

Self-catheterization is quite effective and safe in many persons with overflow incontinence. Typically, a catheter is inserted every 2 to 4 hours. This permits whatever urine that has accumulated in the bladder to drain into the proper receptacle.

Indwelling catheterization is a last-resort to treatment of incontinence, even for bedridden patients. Indwelling catheters can serve as a source of irritation and infection.

Incontinent patients must follow strict **hygienic measures**. Skin that is macerated with urine can colonize bacteria and fungi, leading to serious pathology. The presence of urine can also be a cause of foul odors. Various topically-applied barrier products are available to protect the skin against the damaging effect of urine. They also permit cleansing the skin without the drying action of soap.

Bladder control is, in part, a voluntary process. It therefore can be improved by learned activity. Incontinent men and women can often develop better control of incontinence by **exercising** the pubococcygeus muscle (the internal muscle that controls urine flow) by tightening and relaxing it. These "Kegel Exercises" were originally developed to aid women after childbirth. The muscle can be identified by voluntarily stopping and starting urine flow during voiding. A typical program includes three sessions a day, with 10 to 15 tightening/relaxing episodes a session. Benefit is reportedly seen in 3 weeks, but more likely in about 3 months.

Advising Patients on Incontinence

Incontinent persons are often too embarrassed to discuss their problem. They erroneously believe there is a stigma associated with it. Elderly women, for example, may use sanitary pads because they are ashamed to mention their incontinence.

Pharmacists can help remove this stigma by listening carefully and empathetically, advising appropriately, and maintaining a complete inventory of incontinence products. This is sound advice, professionally and economically.

Table 2

Commercially Available Urinary Tract Antispasmodics		
Generic Name	Trade Name	Dosage Forms(s)
Flavoxate	Urispas	100 mg tablet
Approved indications: symptomatic relief of dysuria, urgency, nocturia, suprapubic pain, frequency, and incontinence as may occur in cystitis, prostatitis, urethrocystitis/urethrotigonitis.		
Oxybutynin	Ditropan	5 mg tablet 5 mg/5 mL syrup
Approved indications: relief of symptoms associated with voiding in patients with uninhibited neurogenic and reflex neurogenic bladder.		

Incontinence products are the second fastest growing category (exceeded by home testing products) of home health care goods sold in pharmacies. One estimate pegs annual sales for 1990 exceeding \$1.5 billion.

Incontinence can be worsened by constipation. Constipation may be exacerbated because some persons believe they should limit their intake of fluid. A high-fiber, high-bulk diet with adequate fluid intake will be helpful.

Weight reduction may be useful for incontinent obese persons. Reduction of 5 to 10 percent of body weight can alleviate intra-abdominal pressure sufficiently to relieve incontinence.

Caffeine-containing beverages and alcohol both have diuretic activity. These should be limited, or eliminated entirely. Some foods which reportedly cause diuresis in susceptible individuals include chocolate, highly spiced foods, sugar, tomatoes, honey, and milk. The effect is not universal. An individual may want to selectively eliminate one or all these items from the diet to see if the condition improves. While some OTC products, such as antihistamines with strong anticholinergic action, or decongestants with alpha-adrenergic activity may cause urinary retention, incontinent patients should be dissuaded from such self-treatment with them until they have been evaluated by a physician. Both drug groups can cause severe adverse effects, especially in elderly persons, and both are contraindicated in some. Moreover, drugs that treat one type of incontinence (e.g., urge) can accentuate other types (e.g., overflow).

OTC artificial saliva and artificial tear products can be recommended for persons taking prescribed drugs that have anticholinergic activity and therefore dry the mouth and eyes. These conditions are especially common in the elderly. Due to the discom-

fort these drugs cause to the mouth and eyes, patients may not take them properly. Use of artificial saliva and tear products may assure compliance with prescribed medication regimens in such patients.

Sources of support for incontinent individuals can be obtained by contacting "HIP" (Help for Incontinent People), Dept RBC, P.O. Box 544, Union, SC 29379; or The Simon Foundation, P.O. Box 835 KC, Wilmette, IL 60091. Both groups were established to promote public and professional education about incontinence.

Dickinson's Pharmacy

Jim Dickinson

The "non-participating pharmacy." Every pharmacy's pricing and billing practices are supposed to be the free and independent product of each owner's unassisted policy-making; the law requires it.

Yet, increasingly, many pharmacies seem to "go with the flow" of what the market appears to have established, without giving specific situations much independent thought.

What happens if, in a particular case, a pharmacist decides not to "go with the flow," but to instead become a "non-participating pharmacy?"

A minority of such pharmacists have done this, deciding that signing Plan X's "participating provider agreement" would amount to an assignment of the pharmacy's right to full payment, in exchange for the doubtful "privilege" of fixed-fee, AWP-minus reimbursement.

One such pharmacist, Etna (PA) independent Bob Matesic says he has found that the better way to go is to help his regular patients (with whom he has obviously established a mutual trust) submit their own claim to the carrier for his usual and customary charge.

Then he collects from the patient when they are reimbursed. All major plans accept such direct-pay patient claims.

Non-participating pharmacies such as Matesic's may therefore raise their average reimbursement per Rx by escaping participation contracts that bind them to AWP-minus and fixed-fee formulas.

To avoid revealing Matesic's actual numbers, I will hypothesize a theoretical case to show how his idea might work in practice.

Say a pharmacy buys a 100-tablet bottle of Maxzide-25 showing an AWP of \$30.03; a 30-tablet fill from that bottle would round out to \$9 ingredient cost to the program plus (say) the program's fixed \$2.75 fee for a reimbursement of \$11.75, which does not reflect the pharmacy's administrative costs of billing and being audited from time to time.

Under Matesic's alternative, that same quantity of Maxzide-25 might be billed to the patient at (say) \$31.56; the plan pays 80% of the actual charge to the patient and deducts an additional \$5 copay; when paid by the plan, the patient then pays the pharmacy \$20.25 (i.e., 80% of \$31.56 equals \$25.25, minus \$5 copay)—which is almost 72% more than the pharmacy would have received if it had been a "participating pharmacy."

When we put Matesic's idea to Bob Johnson, CEO of PCS, he was skeptical that most pharmacists would want to trust their patients that far, but he acknowledged that Matesic seemed to have "found a way around the system."

Matesic bridled at that expression—it implied under-handedness, when "to the contrary, I think I've found out how 'the system' has worked right from the start!" Johnson said that 4% of PCS' claims come from non-participating pharmacies that could be doing just what

Matesic is doing.

Of 1,100 pharmacies dispensing for third-party beneficiaries in Western Pennsylvania, Matesic told us his is one of only three that deal this way.

Johnson predicted that if a substantial number of stores began operating as non-participating pharmacies, it would send plan sponsors' costs up, and they would respond by imposing higher copays and deductibles.

The cost of processing paper claims from patients is "significantly higher" than electronic claims, Johnson said; PCS charges plans \$2–\$2.50 per paper claim, compared with 75–90 cents per claim processed by ReCap.

He saw no prospect of processing patient-reimbursement claims through a pharmacy terminal and ReCap to reduce paper claim costs.

Matesic sees the pharmacist's "personal touch" with the individual patient as the key to his success; being a non-participating pharmacy would not work without it.

In his case, the patient fills in the claim paperwork in his pharmacy, and he mails it to the plan for the patient. The patient picks up his or her medication without payment, and Matesic waits as long as it takes for the patient to pay. Trust is obviously the linchpin of the whole arrangement.

On a brief visit to his pharmacy, we could easily see why. We saw Matesic spend five minutes talking an asthmatic patient out of buying a

\$6 OTC antihistamine. You should try a saline gargle each night and cracking your bedroom window to provide some fresh air circulation instead, Matesic advised. The patient took a bit of convincing but left empty-handed and apparently happy. Somebody has to pay for that kind of patient care in any neighborhood, or the people have to go without. Matesic is able to do this because he has a successful, high-touch pharmacy business. And it's not as if he has no competition; within a three-mile radius, he has two Giant Eagle supermarket pharmacies, three Thrift Drug chain pharmacies, one Medicine Shoppe and four independents.

Matesic would not reveal his client base, other than to say "it's over 100 and less than 500." He accepts no welfare prescriptions, but will fill "pro bono" in an emergency. He also stocks no generics, and thus advertises that his pharmacy is "exempt from Pa. generic drug law." Matesic asserts that only once has a patient's claim been adjusted down by a carrier: on that occasion, the third-party plan paid AWP plus 50%, with no fee.

This feature is presented on a grant from "Dickinson's Pharmacy—The Independent Voice," a professionally stimulating 8-page monthly newsletter available from Ferdic, Inc., P.O. Box 848, Morgantown, WV 26507-0848 at an annual subscription fee of \$45.

Landmark Study Released on Future Role Pharmacists

A landmark study commissioned by NACDS and conducted by SRI International provides the first unbiased and independent analysis of the future role of the community pharmacist and the profound effect that policies now being debated would have on the practice of pharmacy and the provision of health care services in this country.

The study's conclusions and rec-

ommendations have major implications for the future of pharmacy education and manpower. SRI International is an internationally-respected independent research organization based in Menlo Park, Calif.

A key recommendation of this landmark study, stated NACDS President & CEO Ronald L. Ziegler, is that "educators, pharmacy professional organizations, and the American Council on Pharmaceutical Education should re-evaluate their position on the necessity of a six-year entry-level education for generalist community pharmacists."

Ziegler emphasized that the SRI study recommends that "ACPE and other educators should withdraw pressure on pharmacy schools to eliminate the five-year entry-level program."

This major study was commissioned by NACDS to provide an unbiased, overall strategic analysis of the future practice of pharmacy in the community setting. The study was recommended by the Association's Pharmacy Education Advisory Committee, a blue-ribbon panel consisting of deans and professors from leading schools of pharmacy.

Importantly, SRI's analysis indicated that the most likely role of the future community pharmacist would be an expansion of the current role to one of a "drug use counselor." According to this scenario, pharmacists would spend the majority of their time counseling patients on the use of prescription and over-the-counter medications and overseeing drug distribution and control.

SRI further determined that the education necessary for a community pharmacist to gain the needed competencies to play an expanded role in drug use counseling should take no more than five years to complete.

Mandatory implementation of Pharm.D. programs would not only be unnecessary, according to SRI, but would "severely exacerbate" the current pharmacy manpower shortage. This current shortage of some 15,000 pharmacists (8.2%) is expected to more than double by the

year 2010, according to SRI. However, mandatory implementation of Pharm.D. programs would exacerbate this shortage to 19,000 (9.4%) in the year 2000 and 46,000 (19%) by 2010.

Consistent with NACDS's interpretation of the SRI findings, the NACDS Board of Directors resolved at its December 5 meeting in New York City that "NACDS strongly supports the continued offering of a five-year degree in the best interest of the general public and community pharmacy."

The Board of Directors also resolved that "NACDS strongly opposes any attempts to mandate a six-year degree as the sole degree for pharmacy practice."

Among the findings of this landmark study are the following.

- There is substantial evidence that pharmacists can increase the quality of life of patients and reduce overall health care costs by counseling patients on the use of prescription and OTC drugs.
- Community pharmacies distribute the majority of prescription medications and demonstrate interest in providing pharmacy services in addition to value or discount prices. SRI noted that a number of chain drug stores are removing barriers to effective patient/pharmacist interaction such as elevated prescription departments.
- Physicians, through the American Medical Association, will strongly resist "encroachment" upon their profession by pharmacists. SRI pointed out that the AMA is "unequivocally opposed" to the practice of therapeutic substitution by pharmacists, and is also opposed to the diagnosis of disease conditions by pharmacists and to duplication of the prescribing role in the general practice of medicine.
- The deans of the nation's schools of pharmacy are di-

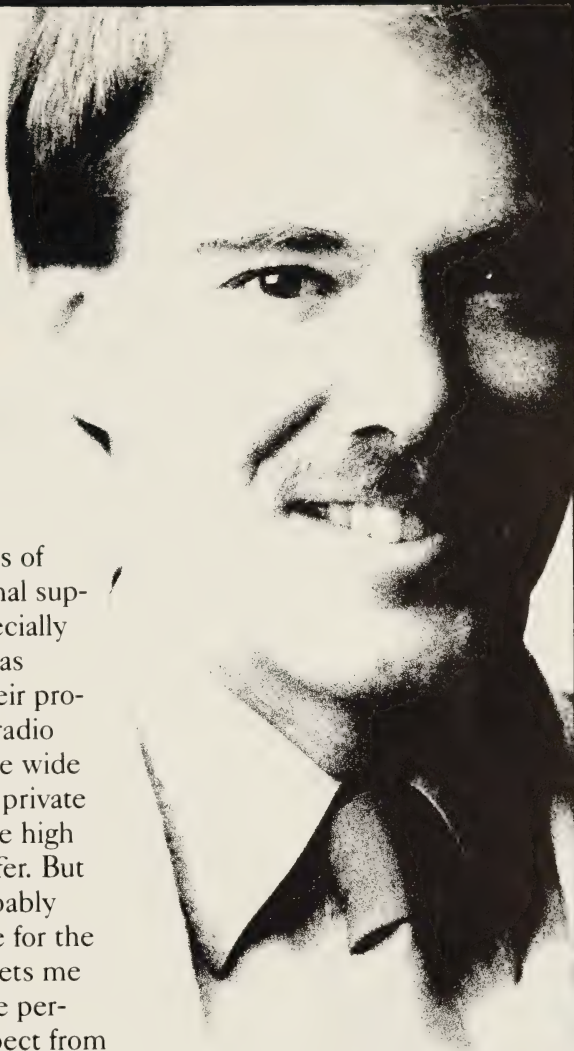
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Scott Rickards

SCOTT RICKARDS
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vided in their support for a six-year Pharm.D. education requirement. Of the deans interviewed by SRI, 40% favored the six-year minimum, 25% opposed such a requirement, and about one-third did not necessarily support such a requirement but would go along with it. One reason noted for opposing the requirement is that the additional educational expense of converting 6,000 students from five-year B.S. graduates to six-year Pharm.D. graduates would be \$90-100 million per year.

- Community pharmacy has social and economic problems in implementing its newer patient care roles. These will not be solved by science, additional scientific education, or an additional year of clinical experiential education. The profession should seek solutions through improving practitioners' performance of appropriate patient care services, setting standards for generalist community practice, and seeking payment for such services.

Based in Alexandria, Virginia, NACDS represents 155 chain drug corporations operating more than 24,000 retail pharmacies which employ 65,000 pharmacists and more than 450,000 personnel nationwide. Chain drug stores are the leaders in the retail drug store industry, representing the largest component of this more than \$60 billion market. The NACDS membership also includes more than 900 suppliers of goods and services to the chain drug industry.

World's First Chair in Geriatric Pharmacotherapy Endowed

One million dollars has been pledged to the Center for the Study of Pharmacy and Therapeutics for the Elderly at the School of Pharmacy, University of Maryland at Baltimore, to establish an endowed chair in Geriatric Pharmacotherapy. This will be the first such chair in the world.

Geriatric Pharmacotherapy is the health care science which aims to achieve safer and more effective drug use for the elderly by matching the patient with the most appropriate drug and dosage form.

The chair, to be named the "Parke-Davis chair in Geriatric Pharmacotherapy," was announced today (Dec. 13) by Joseph E. Smith, president of Parke-Davis, a division of Warner-Lambert Company, at a ceremony at the School of Pharmacy.

The chair is the culmination of more than 10 years of partnership between Parke-Davis and the School's Center for the Study of Pharmacy and Therapeutics for the Elderly. The endowment recognizes the contributions of the center and its founder, Professor Peter P. Lamy, Ph.D., Sc.D., to the field of geriatric pharmacotherapy.

Dr. Lamy is internationally known in this field. He is the director of the center, which was established in 1978—the first such center in any pharmacy school in the United States.

"This chair recognizes the extraordinary productivity of a decade

of partnership between an outstanding pharmaceutical firm and a vital academic institution," said David A. Knapp, acting dean of the School of Pharmacy. "The creation of the Parke-Davis Chair in Geriatric Pharmacotherapy not only assures the continuation of this partnership across generations, but also focuses attention sharply on an area that cries out for nurturing—the use of medications by older persons."

Parke-Davis President Smith called the work of the center an example of what can be accomplished when industry and academia work together, "especially when the goals are clear and the mission is important." He said the chair was a milestone for geriatric care.

Joseph D. Williams, chairman of Warner-Lambert, said: "The nation's health rests in good hands with dedicated professionals such as Dr. Lamy and his associates."

The Center for the Study of Pharmacy and Therapeutics for the Elderly was established in 1978. Its drug education programs have attracted a national following among health care professionals. Brochures and award-winning TV programs have educated millions of senior citizens.

The announcement of the gift comes on the eve of the 150th anniversary celebration of the School of Pharmacy, which was founded in 1841, and the 125th anniversary of Parke-Davis, which was established in 1866.

The gift will be recorded as part of the Campaign for Maryland. Together, the institutions of the University of Maryland System are seeking \$200 million in private support in a five-year fundraising campaign, announced in October 1988.

To date, more than \$140 million has been pledged.

Geriatric pharmacotherapy is the branch of pharmacy study that aims to reduce the risk of drugs and enhance their safety and effectiveness for the elderly. Reducing the risk results from examining and adjusting a variety of variables that might deal with the patient (age, sex, chronic disease history), the drug (dosage, form), or other aspects (the monitoring process, the patient's nutritional status, etc.).

The need for continued work in this field has been clearly echoed recently by various sources—including DHHS Secretary Louis Sullivan, the Institute of Medicine, the American College of Physicians—all pointing to multiple drug use as a major risk factor for older Americans.

The Office of Technology Assessment has stated that drugs are probably the most efficient treatment modality for chronic disease management—yet, those over 80 years-old are likely to receive 21 or more prescriptions annually. In addition, the use of over-the-counter (non-prescription drugs) is rising, partly because more and more prescription drugs are being switched to non-prescription status.

All totaled, those 60 years-of-age and older (17% of the population) receive close to 40% of all prescription drugs and take almost one-third of all non-prescription drugs. About 95% of older adults take medication without supervision, and 86% of this age group have one or more chronic disorders.

The School of Pharmacy at the University of Maryland at Baltimore is a national pioneer in addressing the problems of geriatric drug use through study and outreach efforts. With assistance from Parke-Davis, it

created the Center for the Study of Pharmacy and Therapeutics for the Elderly in 1978, and later established the Parke-Davis Center for the Education of Elderly.

The combined efforts have as a goal to:

- Advocate the correct use of drugs among the elderly;
- Improve communications between the health care provider and the patient or caregiver;
- Train the family caregiver in correct medication management;
- Foster an understanding that the patient or caregiver must be active participants—not passive recipients—in the therapeutic regimen.

The direct effort has been supported by:

- Eldercare News—a quarterly newsletter, abstracting the geriatric/gerontology literature. More than 38,000 health care professionals receive it;
- Video Tapes—four tapes have been produced on the elderly. One, "Medicated Generation," has been shown on PBS in 42 states;
- Presentations—by School of Pharmacy faculty and Parke-Davis staff in all 50 states;
- Pamphlets—17 pamphlets, addressing the particular needs of the elderly, have been produced and are available free of charge.

From more than a decade of cooperation the combined efforts of Parke-Davis' ElderCare Program and the School of Pharmacy's Elder-Health Program have assisted close to 17,000 elderly; 7,000 pharmacists caring for the elderly; 800

pharmacists specifically involved with care for the rural elderly; and hundreds of physicians, osteopaths, nurses, and social workers.

The knowledge gained through these efforts has been incorporated into the curriculum at the School of Pharmacy, and the School's pharmacy faculty have helped to establish similar programs throughout the country.

The announcement that the Parke-Davis Chair in Geriatric Pharmacotherapy will be established in the School of Pharmacy, University of Maryland at Baltimore is a crowning achievement in this cooperative effort.

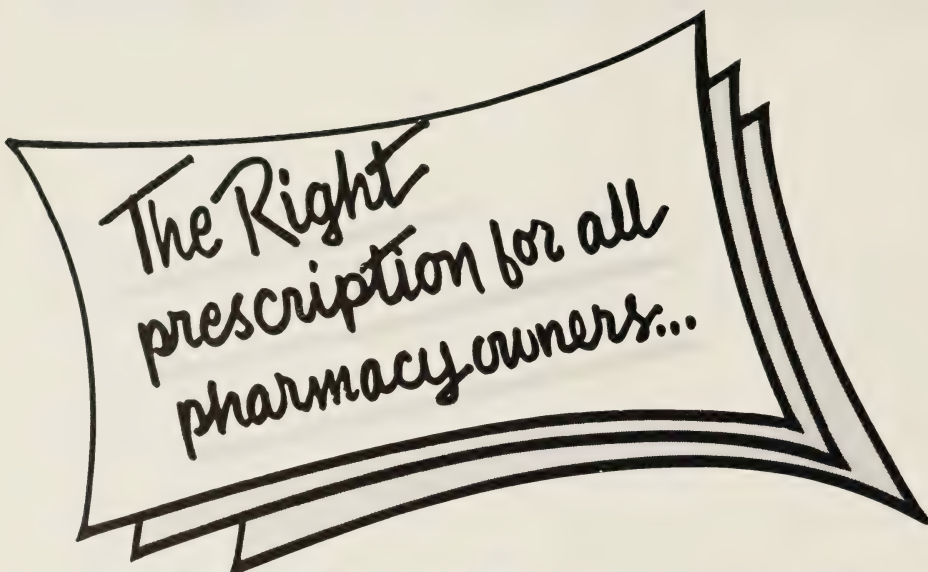


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How to Hire the Right Pharmacist

This is a subject most of us would like to avoid. Hiring the wrong person can be devastating to your business. You can control how your patients perceive your pharmacy when you are there, but what about when you are not? The purpose of this article is to be your guide in hiring the right pharmacist.

Step 1—The Ad.

Newspaper advertisements are just one of your options. There are advantages and disadvantages to this method.

Advantages: When worded correctly, newspaper advertisements can be cost effective. An effective ad is not the cheapest, smallest ad money can buy. A very small ad is often overlooked. A large display ad is ok if you have a large budget, but is often not cost efficient. Before you write your ad, think about who you want to answer the ad. Is the job entry level, or are you looking for very specific skills. Addressing these requirements in your ad will eliminate wasting time interviewing unqualified candidates.

Disadvantages: Even a well written ad will produce many unqualified applicants. This results in lost time spent on interviewing unsuitable candidates.

The best pharmacist may not answer a help wanted ad. This candidate is concerned about jeopardizing his or her current employment. Search, resulting in loss of employment.

Referrals—The “network” approach to finding the right pharmacist is often successful. It is inexpensive, and you have a built in reference network for checking past employment history. The disadvantage to most pharmacy owners is the size of their network. A small referral network will have less success than a large one.

Direct mail—A list of pharmacists is available for a small charge from the Board of Pharmacy. They will provide this list on computer paper or on mailing labels. The list can be generated by zip code (enabling you to mail to pharmacists near your store) or alphabetically. The computer paper list will also list the date the pharmacist graduated, whether by license or reciprocity, and if the pharmacist has ever had their license suspended or revoked. The disadvantage of this method is the large volume of paperwork it can generate.

Agencies—The biggest advantages of an agency are the size of their networks, and the quality of pharmacist provided. They can provide the pharmacist that would never answer your ad, but would be ideal for your

pharmacy. The disadvantage of an agency is the cost. An agency will charge you a percentage of the pharmacist salary for its fee. While your initial costs will be greater, many agencies give a money back guarantee on their pharmacist, eliminating the risk for you.

Step 2—The Interview

For many employers, the interview progresses as follows: The candidate fills out an application, the owner looks it over, verifies past employment, and hires the pharmacist. This will *not* help you get the right pharmacist.

After placing an ad, determine the best time for your interviews. This means *not interviewing when you are on duty*. If you have no time to interview when your store is open, consider interviews prior to or after business hours, or bring in a relief pharmacist for a few hours. You cannot focus on your candidate with the phone ringing, patients waiting, and employee's interrupting your interview.

Document the Candidate from the Beginning

1. Start with your initial impression on the phone. Does the pharmacist sound professional on the phone? If not, your patients and physicians will get the same impression?
2. Did the candidate arrive on time? If punctuality is a problem at the interview stage, it may also be when this individual is your pharmacist.
3. After giving your candidate an application, leave the room. While your potential pharmacist is filling out your application, record your initial impressions. Is the pharmacist clean and neat. Does this person present the professional image you want your store to have?
4. Have a list of questions ready before your pharmacist arrives and stick to your list. Other questions may arise, but it is important not to get side tracked.
5. You will want a *detailed* employment history. If there are any gaps in the employment history, insist on filling them. You do not want a pharmacist who is unwilling to tell you about any of their previous jobs.
6. Insist on at least three pharmacist references. These people should not have been previous employers.

7. Make a photo copy (if you have a copy machine) of the drivers license and pharmacy wallet card of your candidate.
8. After the interview, again document your impressions. Pre interview and post interview impressions will be a valuable tool should you have trouble deciding between two or more candidates.

Verify Everything!

This not only means calling the previous employers and getting their impressions, but also *verifying the pharmacists license*. One phone call to the Board of Pharmacy will determine if the pharmacists license is in good standing, and if it has ever been suspended or revoked. Some pharmacists would not hire anyone with a suspension on their license, and other owners are willing to give the individual a second chance. Only you can decide which way you feel about this issue, but if you find out about a suspension you can at least ask the candidate about the circumstances and make your own decision.

If verifying references is not possible, you can always hire a company to do a background check. This is expensive, but for a pharmacist who has moved from another area, it may be a valuable option.

Schedule Another Interview

Once you have narrowed your choice down to a few pharmacists, bring them back in one more time for a second interview. This is a big decision you are making, and you will need this second chance to talk with your potential pharmacist. Remember, every time this person works when you are not there, your business is in their hands. The years of good will you have built up could be easily enhanced or destroyed. This interview should be less structured and shorter than the first one. Just talk about what you know—pharmacy.

Step 3—The Offer:

You now have narrowed your search to one pharmacist. This is the person who can step into your shoes when you walk out the door. You know you can go on vacation and not worry about your business with this professional running the store. You must now make this individual an offer that will be accepted.

Know Your Competition

You are competing for this pharmacist with chains and independents. Call some of your friends in both sectors, and see how much other pharmacist in your area are receiving. Salary is only one aspect of the offer. Full time pharmacists will receive health benefits, paid vacation, and a performance bonus. *This is not the time to economize*. Don't be afraid to offer above the going rate for an excellent pharmacist. You can probably find a pharmacist who will work for a rate below the current average, but you will get what you pay for. A good pharmacist will pay for himself in building customer loyalty for your store and peace of mind for yourself. Your patients will be pleased to have *two* pharmacists they like and trust, and will not worry when you cannot be there.

About Written Contracts

Many pharmacists are now asking me about written contracts. They are concerned that considerations promised to them will not be fulfilled. I cannot advise if you should or should not offer a written contract. I can, however, tell you what your pharmacist is looking for in the contract.

Your pharmacist is interested in written confirmation of guaranteed employment as well as all salary considerations. Make certain you protect yourself! Many owners insist on a 90 day trial before signing any contracts. You can tell your new pharmacist this will protect them as well as you. If you decide to offer a written contract, have your lawyer check it first. Remember, we are pharmacists, not attorneys.

The hiring method outlined in this article is more detailed and certainly takes longer than the process most pharmacists currently use. If you are wondering whether this procedure is worth the effort, ask yourself this question. If one of my employees were responsible for hiring pharmacists, which method would I want them to use?

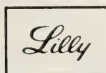
Glenn Lichtman is a pharmacist and a member of the Maryland Pharmacists Association. As own and founder of Pharmastat Inc., Glenn has interviewed several hundred pharmacists for his company. The information in this article was drawn from techniques developed over the course of those interviews.

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Pharmacist's Role in the Home Health Care of the Elderly

Omolola Elliott

Aging is a biological process over which people have virtually no influence or control, though it is a social and possibly a medical process over which patient and provider can and should exercise a great deal of control.

A vast majority of patients over 65 years of age have multiple disease states that require the use of many drugs, usually on a long-term basis. There is thus a greater likelihood of drug-drug interactions as well as adverse side effects.

Many live alone in a depressed state, with ailments that impair their mental and physical status. They tend to omit doses, commit dosage errors, and suffer from eye conditions that make it difficult to read label instructions. Their arthritic hands have trouble opening vials, with or without child resistant closures. They may be malnourished, for reasons ranging from poor dentition to poor finances.

They use laxatives frequently and fluids inadequately. Therefore, the physical deterioration of the aging causes abnormal responses to many drugs. This is where the pharmacists fit in, by monitoring patient drug regimens and nutrition; counsel patients about compliance, side effects, allergies and sensitivities.

They also communicate findings to nurses and physicians; create procedures and forms to achieve these goals; to cooperate with all health professionals involved in improving patient care and to enter evidence of monitoring and evaluation into the appropriate record.

With all the above implemented properly, drugs can be the most cost-effective and cost-beneficial modality of disease management in chronic care.

According to federal regulation, a home health agency is an organization which is primarily engaged in providing skilled nursing and other therapeutic services on a part-time or intermittent basis to patients in a place of residence used as the patient's home. This is an area where pharmacists have made a big difference in the health care of the elderly.

Some of the role models include Jack Katzoff, PhD, who has had a long career in hospital pharmacy. Cur-

rently, he is a consultant and community pharmacist in Los Angeles, CA and says "I make my own evaluations and recommendations. A copy of which goes into the permanent record and is given to the supervising nurse for her information, discuss some of my more important findings with the staff, add whatever pertinent drug-related information seems appropriate." (Katzoff J. A pharmacist in a home health agency. *J Am Pharm* 1980; 29(Aug):52-54.)

"A person to person pharmacy", those words appear on every prescription label, every receipt, every bag, on just about every piece of paper used in Craig M. Bell's Pharmacy, San Antonio, Texas. His employees are another reason for his success. The cashiers and delivery persons are senior citizens. The result is a natural empathy. Employees and customers all talk about the same "good old days", the same aches and pains, the same problems with grandchildren. Other ways in which he is developing his pharmacy as a health resource for senior citizens involve nutrition and home health care.

Nutrition is a natural area for pharmacy. The close relation between diet and health presents special problems for the elderly people. It is not always easy to cook for one, nor to go out for every meal. For an elderly person who cannot manage an adequate diet via regular meals, what could be better for the skipped meal than a food supplement combining all the vitamins, minerals and calories necessary in one eight-ounce milkshake. (Bell CM. What the elderly want above all is the personal touch. *Am Drug* 1985; 192(Dec):58-59, 62-63.)

David Hicks, a pharmacist in suburban Chicago, added a home health agency with three offices to his busy practice in community and nursing home pharmacy. Hicks has contracted for 2-3 hours each month retracted reviewing drug regimens and about 1 1/2 hours conducting in-service training programs. He has arranged for the nurses to receive continuing education credit for these programs. (Gerson CK. Pharmaceutical services in home health care. *Am Pharm* 1980; 20(Aug):50-51.)

Don Griffin, a pharmacist enrolled in the graduate program at the University of Georgia School of Pharmacy, has extended his area of research interest to act as a consultant for a hospital home health department. He accompanies staff and evaluates and educates patients with respect to their medications. (Gerson CK. Pharmaceutical services in home health care. *Am Pharm* 1980; 20(Aug):50-51.)

Although, pharmacists try their best to implement all the above policies, some of the problems usually encountered from the patients are as follows:

Hearing loss is common among the older population and another challenge to communication, therefore becomes an important factor in lack of socialization for the mobile elderly. To the patient suffering a decrease in hearing ability, words spoken quickly are lost or garbled. However, the pharmacist's clear, careful instructions and interested responses to questions can reassure the patients. It can ease their anxiety and help them develop sensitive feelings about correct use of medications. Knowledge of the use of drugs and confidence in their self-care capabilities ultimately help raise patient's self-esteem.

Consider the arthritic patient for a moment. A majority of elderly live with the effects of arthritis in one form or another. To the person suffering with arthritis, pain is a daily way of life. A walk to the store can be a painful experience. The hard floor underfoot can feel like rocks under swollen, arthritic feet. The arthritic victim is a likely candidate for use of OTC pain killers on a regular basis. Questioning them on drugs they currently take is extremely important when new medications are prescribed.

The problems of decreased manual dexterity often increase with age. For this reason safety caps are often entitled "enemies of the aged". To the elderly, arthritic patient, the difficult safety cap can be a life-endangering experience. Giving them choices of medicine container will make medicine taking as comfortable and as safe as possible.

Longevity and a high quality of health are made possible through the use of medications. The geriatric patient's response to drugs is less predictable than might be expected, it is very important for the pharmacist to remind the elderly not to use someone else's medication.

Among the elderly, drug compliance is far below the optimum level. Two factors which contribute to the low level of drug compliance are lack of knowledge and lack of interest in taking care of oneself. Problems such as health, income, housing, role loss, loss of friends and family place emotional demands on aging individuals. Exacerbated by the discrimination of our youth-oriented society, a sense of psychological alienation often takes over.

Recognized as an expert in pharmacology, the pharmacist is most directly involved with the medications the elderly patient receives. This is an ideal position for

expanding the knowledge-base and self-esteem of the individual through positive communication.

Comprehension is essential to positive communication. Medical terminology often confuses and frightens the older patient. It is important to speak in language and terms that are understandable, on an adult-adult level. This measure of respect builds trust and confidence which are the major factors to successful communication.

Sight losses necessitate special consideration for positive communication. Labels types in large print are easier for all older people to read, and are essential for some. If large print is not available, typing in capital letters is helpful. The clarity of an auxiliary label can impede or expedite drug compliance for the elderly patients. For example, whether or not the patient can easily read, "Take with food or milk", or "Take on an empty stomach" may determine how the patient will be affected by the drug or if they will continue to take it at all.

Another important aspect essential to the patient's compliance is the pharmacist's attitude and this was demonstrated by the following experiment. In a large metropolitan city, a neatly groomed middle aged woman patronized 24 pharmacies within one week. She received, with little exception, prompt, courteous attention. Her questions were responded to in a professional manner, with respect to her as a person.

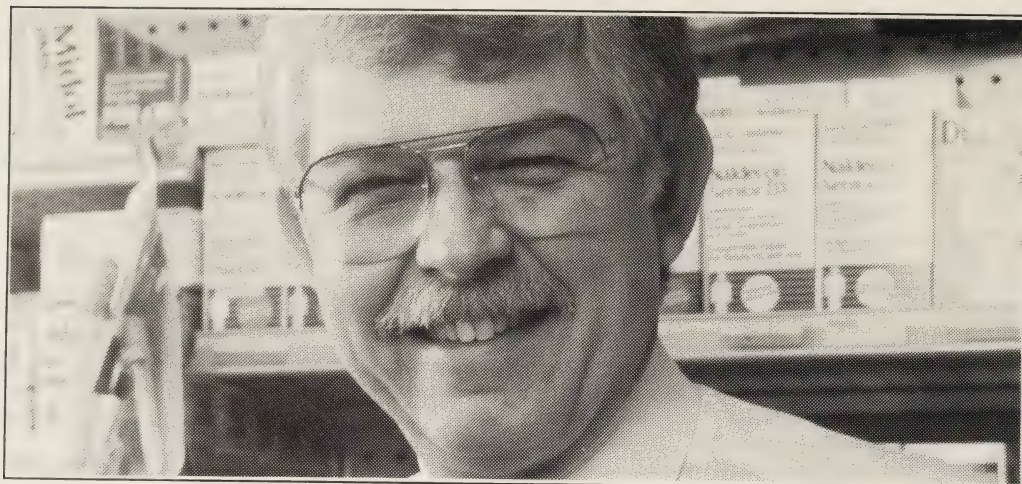
The same woman, wearing a gray wig, carrying a cane and looking approximately 20 to 25 years older than her years, patronized the same stores the following week. This time the prompt attention was not delivered. With little exception, she waited longer. Her questions were responded to, but more often with an attitude of annoyance rather than respect.

Pharmacists who were previously attentive and caring, treated her in a fatherly, patronizing manner with words such as "dearie" and "honey"—words that were never used when speaking to the younger woman. The implications of this interesting experiment are that attitudes are the first modifications a pharmacist should make when preparing for the elderly.

Seating areas, large-typed labels and easy-open bottles are hardly enough if elderly patients are treated in an impatient or patronizing manner. Prompt attention and clear explanation on an adult-adult level reflect attitudes that these patients are worth the time spent with them. Gray hair on one's head is not a sign that they are less as people, only that they are older people and deserve equal treatment. (Reses SSF. The geriatric patient—pharmacy care can make a difference. *Apothecary* 1982; 94(Jul-Aug):34-43.)

Ninety-five percent of all people over the age of 65 reside within the community. Only 5% are institutionalized at any one time. Of this great percentage of community-residing elderly, 75% are termed "well elderly". These "well elderly" face a number of insults that are unique and age related. (Reses SSF. The geri-

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atric patient—pharmacy care can make a difference. *Apothecary* 1982; 94(Jul–Aug):34–43.)

They contend with varying degrees of the normal degenerative processes of old age. The majority of the elderly fall into the zone of small affliction. However, individually the aged person suffers from many chronic conditions manageable only with the drugs.

The older person's level of environmental awareness decreases due to lowered efficiency of a number of organs. Hearing and sight are often limited. Because the physical impairment affects the ability to communicate comfortably, the sociological and psychological ramifications are widespread. Coupled and a multitude of physical problems are the economic complaints which accompany old age.

The pharmacist is the health care professional many of the elderly patients relate to most often. The manner in which the pharmacist listens to a statement, his response, the personal interest he projects, can determine the level of compliance with which the elderly patient follows his/her drug regimen. Through positive communication, the pharmacist can help the elderly enjoy a healthier, more satisfactory lifestyle.

Another important service provided to the elderly by the pharmacist is saving money by purchasing generic drugs. Eighty-four percent of elderly pay for their prescription medications out-of-pocket. Patient's are often urged to buy in 100's because it is cheaper. However, they should ask for a small quantity when starting a new medicine. Always ask for senior citizen discount or ask if their is a less expensive generic of the medication.

OTC drug use is prevalent among the elderly. Not surprising! OTC's are easily obtained. Self-medication fosters a sense of independence. OTC's are cheaper than prescription medications and many elderly grew up using home preparations. Also, OTC's are widely advertised, particularly on television, where elderly get much of their information. Therefore, the pharmacist provides guidelines for product selection. The first step is diagnosing the problem and once the problem and once the problem is diagnosed, they decide if a medication is needed or not. For example, The Common Cold: with medication it may last seven days, without medication it may last a week! Is the medication really worth it?

Pharmacists are also concerned about nutrition, vitamins and minerals. Vitamins can be misused by using it to cover underlying problems, large doses may be toxic and may interact with other medications. It is important for the pharmacist to remind the elderly that vitamins are dietary supplements not subject to strict controls imposed on drugs. They are viewed as drugs and should only be used to prevent a deficiency state or treat a deficiency state.

Attention is most often focused mainly on those OTC's used internally. Nevertheless, it is well to remember that many products are available for external

use that are important to the elderly's well being. Among these are dry skin products, which must be used correctly. The elderly diabetic patient must protect the skin against injury, keep it clean, take care of minor cuts and bruises, and use skin softeners to treat xeroderma.

Many dry skin products are available, including urea-containing products (elderly persons may exhibit heightened tissue-sensitivity to these), products containing vitamins A and D, and emollients. Products that are added to the bath water may make the tub slippery and dangerous for elderly persons with a lessened ability to withstand falls. Creams, although easily rubbed in and easily removed (more patient acceptance), do not occlude the skin and therefore provide little moisture to the skin. Gels, because of their alcohol, can indeed worsen the condition. Best are the petrolatum-based ointments, but they are hard to rub in and may therefore not find patient acceptance.

All these above problems are taken into consideration by the pharmacist when recommending any of the OTC products to the elderly or their providers.

Dry eyes are a major complaint of mainly elderly persons. A disadvantage of products containing either methylcellulose or polyvinyl alcohol is their short duration of action, and treatment failure is often caused by lack of frequent administration. Thus, dry eyes can be treated with artificial tears, but these must be applied often.

Dry, forced heat can heighten the risk to respiratory problems and to dry skin. A humidifier should be recommended, but given the patient with good instructions, since both underhydration and overhydration can be dangerous to the elderly.

Patients with arthritic conditions and pain (both rheumatoid arthritis and osteoarthritis) may be advised to use a moist heat pad. However, in recommending such a product, the pharmacist must be aware that the elderly suffer often from "referred" pain, i.e., a bad knee may lead to pain in the hip, thus application of heat to the hip would not help. One must also be aware that the elderly do not perceive heat as well as do younger people (thus, they may tend to make the appliance too hot) and, if burned, they heal poorly and slowly.

The phenomenon of a large elderly population is one of the most dramatic and influential developments of the twentieth century. Never before in history have there been so many older people numerically and proportionately.

It is therefore not surprising that interest in home health care is on the rise. Many pharmacy schools now work with home health agencies to give students clinical experience. As these future practitioners graduate, they will add their support to this component of patient care. Many people view home health care as an alternative to hospital care, but most pharmacists would like to see that view turned around—that hospital care is an alternative to home care.

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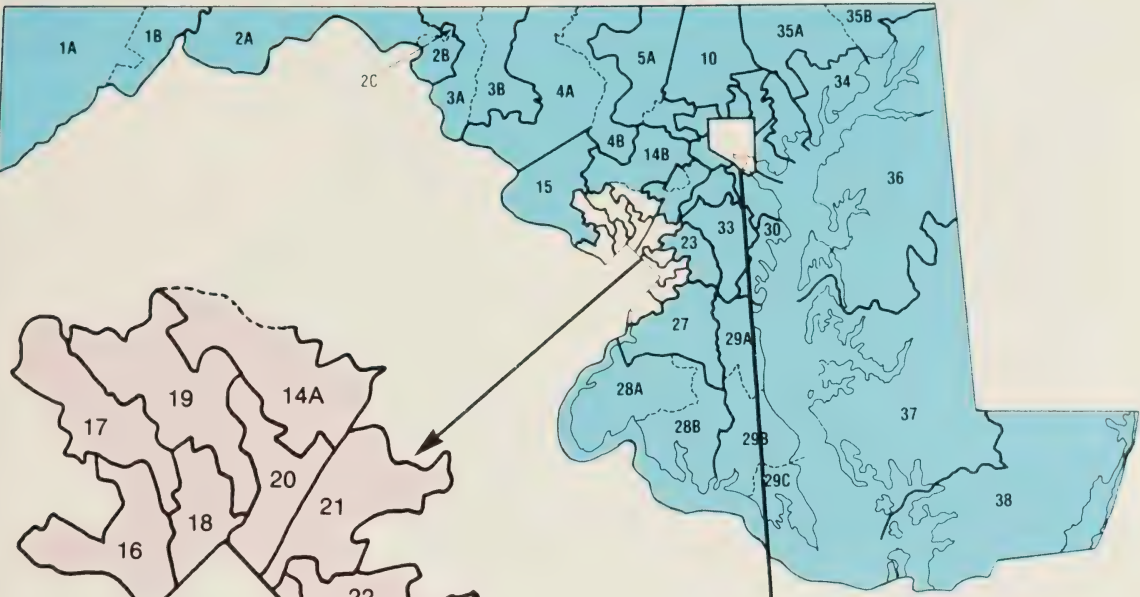
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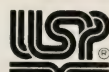
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DRUG PRODUCT QUALITY Review

A PUBLICATION OF THE USP DRUG PRODUCT
PROBLEM REPORTING PROGRAM

No. 15

EXPIRATION DATING OF VITAMINS

Parenteral Nutrients, Nutritional Supplements, Dietary Supplements, Over-the-counter Vitamins, Prescription Vitamins—Some vitamin products are considered to be foods, while other vitamin products are considered to be drugs. Confusing? Many pharmacists think so!

The USP Drug Product Problem Reporting Program (DPPR) has received more than 200 reports on vitamin/mineral products and nutritional supplements. Reported problems ranged from inadequate dissolution to possible product mix-ups, with more than 10% of the reports citing missing information on the product label, especially lack of an expiration date. One California pharmacist reported that a bottle of 1000 Enteric Coated Ferrous Sulfate Tablets 325 mg did not have an expiration date on its label. A pharmacist from Washington reported finding no expiration date on a bottle of 100 Sustained-release Niacin Capsules 250 mg. Similarly, a report was received from a New Jersey pharmacist who stated that a salt substitute containing Potassium had no lot number nor expiration date on its label.

...

USP REVIEW

Expiration dating requirements for drug products are well known to pharmacists. Under section 21 CFR 211.137 of the Federal Food, Drug and Cosmetic (FD&C) Act, **drug products** must bear an expiration date. Drug products are defined by regulation as finished dosage forms with an active ingredient. They may be either prescription items or over-the-counter products. However, the expiration date requirement does not apply to all **over-the-counter** (OTC) drug products. If an OTC drug product is stable for at least three years, as supported by stability data, and if the product does not bear dosage limitations, it may be exempt from the requirement.

The General Notices Section of *USP XXII* (pg. 10) defines similar expiration date requirements for official USP/NF drug products. Furthermore, it is stated, "Where an official article is required to bear an expiration date, such article shall be dispensed solely in, or from, a container labeled with an expiration date, and the date on which the article is dispensed shall be within the labeled expiry period."

A vitamin product for human use is regulated by the Food and Drug Administration as either a food or a drug. In considering whether an OTC vitamin product (nutritional or dietary supplement) is required to bear an expiration date, it must be determined whether the product is classified as a drug or as a food under the FD&C Act. The fact that it is in a dosage form (e.g. tablet, capsule) is not determinative. Unless a product makes a therapeutic claim, a nonprescription vitamin product is usually regulated as a **food**, rather than as a drug. Vitamin products are often labeled as nutritional or dietary supplements. A statement that a product will alleviate symptoms, or will cure or promote healing of conditions, may be considered to be a therapeutic claim. The labeling of a nonprescription vitamin product with a therapeutic claim may result in the product being regulated as a drug. In these cases, the expiration date requirements of the FD&C Act mentioned earlier will apply. USP is unaware of any similar requirements for foods.

The USP is currently exploring the provision of suitable standards, as well as any necessary packaging and labeling requirements, including expiration dating, for vitamin products that are used as dietary supplements. It is hoped that this will help remove some of the current confusion which exists concerning these dosage forms.

To report problems with drug products, or for further information, contact the USP DPPR Program at 1-800-638-6725.



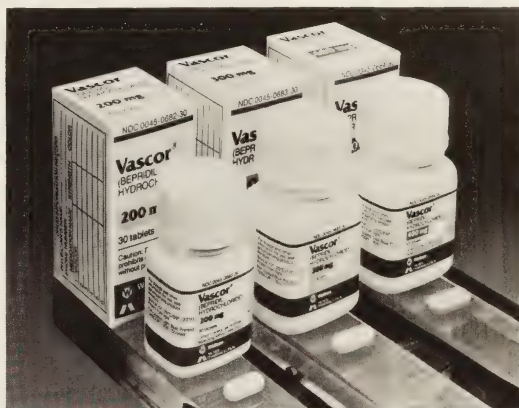
Beginning this month, ICI Pharma will market the beta blocker Tenormin (atenolol) in a new 25mg tablet. Tenormin 50mg scored tablets will be available in a convenient 1,000 count bottle.



Cole's Quality Foods plans to launch a June magazine ad campaign touting its new Garlic Oil capsules with a "no after-odor" guarantee. A 100 count bottle has a suggested retail of \$8.99.



Bristol-Myers Oncology Division has announced that it will market several more of its widely used injectable chemotherapeutic agents with CytoGuard, a patented safety device that reduces the possibility of cytotoxic aerosolization into the environment. Bristol-Myers will automatically ship CytoGuard with Vespid, Paraplatin, and the new 10mg vial of Rubex.



A new once-daily calcium channel blocker, Vasacor (bepridil) is being promoted by McNeil and Wallace beginning March 4. Because Vasacor has caused serious ventricular arrhythmias, it should be reserved for patients who have failed to respond optimally to, or are intolerant of, other anti-anginal products.

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Continuing Education Quiz

The Maryland Pharmacist

MARCH 1991

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by July 1, 1991. A continuing education certificate for one contact credit will be mailed to you within 30 days. Please type or print clearly.

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Is this program used to meet your mandatory CE? [] Yes [] No

Did this article achieve its stated objectives? [] Yes [] No

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Urinary Incontinence

1. Of the following types of incontinence, which reportedly responds best to intermittent catheterization?
 - a. Functional
 - b. Overflow
 - c. Stress
 - d. Urge
2. Stimulation of which subdivision of the autonomic nervous system is most likely to promote voiding of urine?
 - a. Parasympathetic
 - b. Sympathetic
3. The tube that urine passes through on its way from the kidney to the bladder is the:
 - a. glomerulus.
 - b. urethra.
 - c. nephron.
 - d. ureter.
4. The exercise regimen that improves bladder control by tightening and relaxing the internal bladder muscles is referred to as the:
 - a. Cholecyst exercise.
 - b. Fonda exercise.
 - c. Kegel exercise.
 - d. Trigone exercise.
5. Which of the following statements is true?
 - a. When the intravesical pressure exceeds the intraurethral pressure, urine will flow.
 - b. When the intraurethral pressure exceeds the intravesical pressure, urine will flow.
6. All of the following tissues relax when urine is excreted from the bladder EXCEPT the:
 - a. detrusor muscle.
 - b. external sphincter.
 - c. internal sphincter.
7. The group of OTC drugs that is most likely to exert anticholinergic activity is:
 - a. analgesics.
 - b. antihistamines.
 - c. appetite appeasers.
 - d. decongestants.
8. Incontinence caused by drugs is referred to as:
 - a. functional.
 - b. iatrogenic.
 - c. stress.
 - d. urge.
9. Intravesical pressure refers to pressure:
 - a. on the bladder from the outside.
 - b. from the backflow of urine from the bladder to the kidneys.
 - c. in the blood vessels supplying the bladder.
 - d. within the bladder.
10. Which of the following groups of drugs is most likely to be effective in treating stress incontinence?
 - a. Alpha-adrenergic blockers
 - b. Cholinergic stimulants
 - c. Anticholinergics
 - d. Beta-adrenergic agonists

Classified

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"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Horn and Horn Smorgasboard on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (301) 358-7036.

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The Maryland Pharmacist

VOL. 67

April, 1991

No. 4



Separation of Pharmacy and Medicine (1240 AD)

Frederick II, King of the Two Sicilies granted Pharmacy independence from Medicine by imperial edict and established legal responsibilities for each.



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The Maryland Pharmacist (ISSN 0025-4347) is published monthly by the Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201. Annual Subscription — United States and foreign, \$10 a year; single copies, \$1.50. Members of the Maryland Pharmacists Association receive The Maryland Pharmacist each month as part of their annual membership dues. Entered as second class matter at Baltimore, Maryland and additional mailing offices. Postmaster: send address changes to: The Maryland Pharmacist, 650 West Lombard Street, Baltimore, Maryland 21201.

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Winding Down

With three months left in my term as president, my thoughts are wandering over what we finished, what we are doing, and what still needs to be accomplished for MPhA.

Certainly our efforts with continuing education are most inspiring. The jewels of our CE programs are our Midyear—which this year brought out more than 270 pharmacists—and our Annual Convention which set all time records last year. Attending just these two programs gives a pharmacist in Maryland all the continuing education credits they need to meet their legal requirements. I am encouraged by the widespread attraction and acceptance of our programs. If any members have ideas for future programs, please send them to our headquarters.

Our efforts in dealing with the business of pharmacy has been highlighted by the litigation of our counsel, Joseph Kaufman. We have won in the Court of Special Appeals our appeal of the Insurance Commission's decision to permit Blue Cross to charge an administrative fee for processing prescription claims. The Court reaffirmed that "AWP" was an acceptable reimbursement standard for Blue Cross.

Last, but certainly not least, the MPhA is actively involved in a long-range strategic planning process to improve our abilities to meet future challenges. The Long Range Planning Committee plans to release a full summary of their suggested changes in a *Maryland Pharmacist* report soon.

What has to be done? Well, I have lots of ideas and I'm sure you do too! Drop a line to the office and let me know what you want done.

Mark A. Levi, P.D.

President

Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Correspondence Course

Counseling Consumers on OTC Enteral Nutrition Products

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, OH

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, OH

Goals

The goals of this lesson are to:

1. discuss the rationale for enteral nutrition, and describe OTC enteral nutrition products;
2. categorize these products by use, and describe their actions, limitations, and overall utility; and

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3. present important information to communicate to consumers to insure correct use of OTC enteral nutrition products.

Objectives

At the conclusion of this lesson, participants should be able to:

1. select the major food groups for supplying energy to the body, and describe the contributions and relative importance of each;
2. exhibit knowledge on OTC enteral nutrition products, citing their uses and misuses, limitations, precautions, and formulation considerations;
3. demonstrate an understanding of important advice to convey to consumers about correct use of OTC enteral nutrition products.

Many Americans agree that eating right is essential to good health and plan nutritious meals. Enteral nutrition and OTC products to provide it are not as well understood by consumers or pharmacists, even though the same principles apply.

This article discusses enteral nutrition and OTC products in this market. It differentiates between the various products and reviews how to assist consumers in selecting appropriate ones. It provides specific guidelines to follow when counseling consumers to assure compliance and reduce the chance for adverse effects. It also presents points for pharmacists' consideration, to effectively market the prod-

ucts and maximize their opportunity for repeated sales.

Background

Although food is required to sustain life, some individuals may not be able to eat well because of physical or mental impairment, lack of knowledge on good nutrition, or emotional or other considerations to consume sufficient food to assure adequate caloric intake. Or, they may eat an abundance of calories, but still consume a nutritionally-imbalanced diet.

A wide variety of enteral nutrition products are available over-the-counter to ensure that adequate nutrition is met. These products, along with associated supplies, represent one of the most vibrant segments of pharmacy practice. Annual sales are projected to approximate \$900 million in 1990. It is possible that increases in sales will be substantially higher in future years, since Americans are living longer and taking better care of themselves. This will necessitate even greater demand for these products.

While they may seem complicated at first inspection, enteral nutrition products are not difficult to understand. Their ingredients, formulation considerations, and indications are based on sound principles of nutrition.

The Need for Balanced Nutrition

The human body requires nutrition to supply it with energy to operate. Energy is derived from calories provided by the three main food groups: carbohydrate, fat, and protein.

Carbohydrate is the most important energy source for humans. Excessive carbohydrate that is not needed immediately can be stored in muscle and liver as glycogen for later use. Stored glycogen will normally support energy needs for approximately one-half day. After stores are depleted, the body will use fat, then protein, for energy.

Certain tissues, including the brain, blood cells, and kidney, require glucose exclusively for their energy requirements, even when carbohydrate intake is restricted and glycogen stores are depleted. Carbohydrate is readily converted into fat; the reverse reaction is limited. Less than 10 to 15 percent of glucose will be formed from fat during periods of early starvation.

Protein supplies most glucose in carbohydrate-starved persons. Protein is catabolized, and then, through gluconeogenesis (i.e., formation of glucose from noncarbohydrate sources), reassembled in the liver to carbohydrate.

Unlike carbohydrate and fat, the body does not store excess protein. So when protein is catabolized to supply energy, various bodily functions including enzymatic reactions, muscular movement, and organ activity may be adversely affected. Loss of as little as one-third of the body's total protein can be fatal.

Healthy adults require 1,600 to 3,000 Calories per day. Actual requirement depends on the amount of physical activity, age and sex. A serious disease, or other stress, may increase the demand for additional calories. Dietary studies have shown that the distribution of calories in the average American diet is carbohydrate, 46 percent; fat, 42 percent, and protein, 12 percent.

Enteral Nutrition

Enteral nutrition is defined as the supplying of nourishment directly into the stomach. Such feeding is not new, having been described by early Egyptians and others. Primitive enteral nutrient feeding often involved gavage with milk, wine, broth, or other liquids directly into the rectum.

By the late-17th century, oral and nasogastric feeding tubes were used to deliver liquid nourishment directly into the stomach. Liquid flowed by gravity, or by pressure exerted upon it. The broth was commonly pureed meat, vegetables, fruit, eggs, fats, and oils. Or, it consisted of food products supplemented with sugars, cream, and dried milk solids. There was little or no attention given to assuring a balanced intake of essential nutrients.

Modern enteral nutrition products

(Table 1) were first developed in the late-1960s, and led the way to total home nutrition support. Before its development, persons with poorly functioning digestive tracts, or following surgery, were dependent upon paren-

teral administration of nutrients. They received dilute solutions of glucose and amino acids through a peripheral vein, or more concentrated solutions directly into the subclavian vein (hyperalimentation). Either way, they

Table 1
Representative Enteral Nutrition Products

Product (Manufacturer)	Form
Amin-Aid (McGaw)	Powder, Pudding
Citroline (Sandoz)	Powder
Compleat Regular Formula (Sandoz)	Liquid
Compleat Modified Formula (Sandoz)	Liquid
Criticare HN (Mead Johnson)	Liquid
Enrich (Ross)	Liquid
Ensure (Ross)	Liquid, Powder
Ensure HN (Ross)	Liquid
Ensure Plus (Ross)	Liquid
Ensure Plus HN (Ross)	Liquid
Entri-Pak with Entrition (Biosearch)	Liquid
Exceed (Ross)	Liquid, Powder
Forta Pudding (Ross)	Pudding
Glucerna (Ross)	Liquid
Hepatic-Aid (McGaw)	Powder, Pudding
Isocal (Mead Johnson)	Liquid
Isocal HCN (Mead Johnson)	Liquid
Isotein HN (Sandoz)	Powder
Lonalac (Mead Johnson)	Powder
Magnacal (Biosearch)	Liquid
Meritene (Sandoz)	Liquid, Powder
Nutri-Aid (McGaw)	Liquid
Osmolite (Ross)	Liquid
Osmolite HN (Ross)	Liquid
Polydose (Ross)	Liquid, Powder
Precision (Sandoz)	Liquid, Powder
Precision High Nitrogen (Sandoz)	Powder
Precision LR (Sandoz)	Powder
Portagen (Mead Johnson)	Powder
ProMod (Ross)	Powder
Pulmocare (Ross)	Liquid
Renu (Biosearch)	Liquid
Resource Instant Crystals (Sandoz)	Crystals
Ross SLD (Ross)	Powder
Stresstein (Sandoz)	Powder
Sustacal HC (Mead Johnson)	Liquid, Powder, Pudding
Sustagen (Mead Johnson)	Powder
Traumacal (Mead Johnson)	Liquid
Traum-Aid HBC (McGaw)	Powder
Travasorb (Travenol)	Liquid
Travasorb Hepatic (Travenol)	Powder
Travasorb MCT (Travenol)	Liquid
Travasorb Renal (Travenol)	Powder
Travasorb STD (Travenol)	Powder
TwoCal HN (Ross)	Liquid
Vital High Nitrogen (Ross)	Powder
Vitaneed (Biosearch)	Liquid
Vivonex, Standard (Norwich Eaton)	Powder
Vivonex, High Nitrogen (Norwich Eaton)	Powder
Vivonex T.E.N. (Norwich Eaton)	Powder

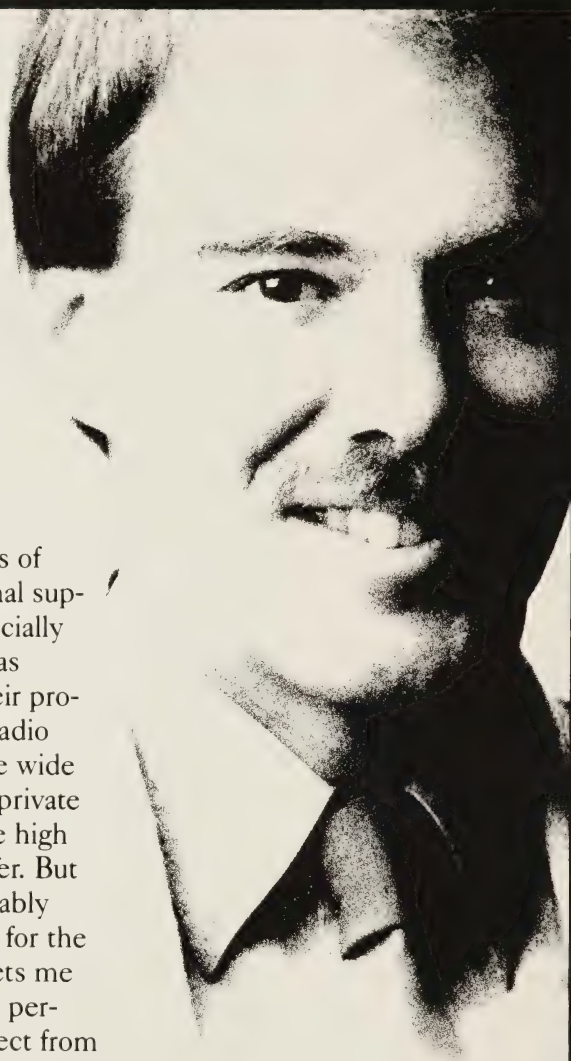
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belong to
Valu-Rite.
There must
be a reason.**

In fact, there are lots of reasons. Promotional support for example, especially now that McKesson has added cable TV to their program of circulars and radio spots. Then there's the wide selection of Valu-Rite private label products, and the high profit margins they offer. But most pharmacies probably sign on with Valu-Rite for the same reason I did: it lets me give my customers the personal service they expect from an independent, along with the low prices of a national chain. That's a combination that just can't be beat."

Scott Rickards

SCOTT RICKARDS
RICKSAVE DRUG
NAPLES, MAINE

McKesson



were dependent on parenteral hook-ups for their nutrition needs.

With enteral product development, individuals could receive all of the balanced constituents of a normal diet — carbohydrate, protein, and fat, and vitamins and minerals — through feeding per os (i.e., by mouth) when they can swallow, or via tube if they cannot swallow or have other gastrointestinal abnormalities. In fact, today, enteral feeding is preferred, whenever possible, over parenteral feeding. It is effective, less expensive, noninvasive, and associated with low potential for serious complications. Parenteral feeding is appropriate for short-term use in a hospital or institutional setting, or when the GI tract is unable to absorb nutrients.

Enteral nutrition products are powder, crystal, or liquid formulations. Solids must be mixed with water or milk before consuming. Some liquids need diluting; others are ready to use.

Some formulae are intended to be used as dietary adjuncts to a normal, well-balanced diet. They are not nutritionally complete, and should not be used as a sole source of nutrition. Other products contain balanced formulations of all required nutritional substances. These can sustain life for as long as would be expected from a well-balanced diet of traditional food.

Enteral nutrition products vary in proportion of carbohydrate, fat, protein, and fiber. They also differ significantly in taste, consumer acceptability, and cost.

Product selection is based on four criteria: caloric needs, other special requirements (e.g., lactose-free diet), palatability, and physician or dietitian recommendations. Many products deliver approximately 1 Calorie/mL. An intake of 1,500 to 2,000 mL of product each day, therefore, can supply 100 percent or more of the Recommended Daily Allowances, depending on the needs of the particular individual.

Product Administration

Enteral nutrition products can be taken orally, or administered through a tube. They can also be given via esophagostomy, jejunostomy, or gastrostomy routes directly into the stomach, duodenum, or proximal jejunum. Most products, especially those that are isotonic, are suited for

administration through a feeding tube. They are also less likely to cause diarrhea, a common outcome of highly concentrated formulations.

Total enteral nutrition (TEN) is the equivalent of total parenteral nutrition (TPN), except that with TEN, nutrients are delivered by tube directly into the stomach. TEN is used when a person has a gastrointestinal affliction that precludes administration of nutrients by the oral route. An inability to swallow (dysphagia) is such an example.

Caloric Requirements and Enteral Nutrition Product Selection

People can be categorized according to their caloric need to maintain an ideal body weight. Daily requirements are based on broad groups, shown below. Reference body weight can be obtained from standard tables, or calculated thusly:

Men: 110 pounds for first 5 feet, plus 5 pounds for each inch over 5 feet

Women: 100 pounds for first 5 feet, plus 5 pounds for each inch over 5 feet

(1) Less than 2,000 Calories with increased protein. This requirement may be suited to elderly or bedfast persons who are physically inactive. It is also recommended for post-surgery patients, and others with infection or fractured bones. These individuals require fewer total calories, while maintaining a need for all normal nutrients, especially protein. Appropriate products which are low in residue include Ensure HR, Sustacal, and Precision HN; or Osmolite, which is low in residue, and also isotonic.

(2) From 2,000 to 3,000 Calories. Most individuals fit into this category, including persons with loss of appetite or cancer. Appropriate products for this group include Meritene, and Carnation Instant Breakfast; Ensure, Resource, and Travasorb, which are low-residue; Osmolite and Isocal, which are low-residue and isotonic; and Enrich, a high fiber product.

(3) More than 3,000 Calories. Persons with severe protein loss who have high caloric requirements include those with serious burns, sepsis, or multiple trauma. They require excessive calories to assist in complete healing. Enteral products that concentrate

1.5 to 2.0 Calories in each milliliter may be recommended. They are also appropriate for persons with anorexia, or cardiac or renal disease, who are on fluid-restricted diets. These products are generally not appropriate as sole nutritional therapy for routine use because of the chance they will cause dehydration. Concentrated products that supply 1.5 Calories/mL include Ensure Plus (normal protein), and Ensure Plus HN, Isotein HN, and TraumaCal, which supply elevated protein; and Isocal HCN, Magnacal, and TwoCal HN, which supply 2.0 Calories/mL and elevated protein.

There may also be special patient needs that require individualization of enteral nutrition therapy. Specific product formulations can be selected to reflect these requirements.

Clear liquid diets (e.g., Citrotein, Ross SLD) are used prior to or after surgery, to provide all needed nutrients and help cleanse the bowel.

Isotonic products (e.g., Osmolite, Isocal) are indicated mainly for tube-feeding where gastrointestinal intolerance for food is of concern.

Low protein formulae (e.g., Amin-Aid and Travasorb Renal, Hepatic-Aid or Travasorb Hepatic) are for persons with renal or liver disorders respectively.

Low carbohydrate products (e.g., Glucerna, Pulmocare) limit carbon dioxide production, so have little respiratory depressant action. Persons with respiratory insufficiency or problems with CO₂ retention, or diabetes mellitus, may benefit from these products.

High carbohydrate polymers (e.g., Exceed) are used to *supplement* a traditional diet, rather than *substitute* for one. They are tasteless, and may be used by athletes and others to add carbohydrate and calories.

Nutrient-dense products are similar to other formulations but yield 1.5 to 2.0 Calories/mL. They are used by persons who have unusually high nutrient needs, or others with hepatic or renal disease who cannot tolerate large volumes of liquid.

Modular products (e.g., Moducal, Polycose and Sumacal, carbohydrate; MCT and Microlipic, fat; and Casec, Promix, and Promod, protein) can be combined as needed, or added to regular food, to provide specific dietary requirements of carbohydrate, fat, or protein.

Predigested or hydrolyzed formulae (e.g., Criticare HN, Travasorb HN, Vital HN) are partially digested proteins. They have been prepared by treating protein with acid or enzymes which hydrolyze them to di- and tripeptides. Persons with damaged intestines or limited absorptive surfaces, or pancreatic insufficiency, may benefit from these products. They are easily absorbed, and have less chance for causing diarrhea. Their taste may not be as palatable as nonhydrolyzed products.

Puddings (e.g., Forta Pudding, Sustacal Pudding) are semisolid products. They may benefit individuals with swallowing disorders who have difficulty consuming liquid formulations.

Pharmacists' Opportunities

The future market for enteral nutrition products will continue to grow. Pharmacists' opportunities will also continue to increase, paralleling the rapid growth in use of these products. Reasons for this upward trend include: (1) government cost-containing programs for reimbursement of hospital costs promoting home, rather than institutionalized, care; (2) an aging population assuring an even greater number of product users in the future; and (3) advances in technology making enteral nutrition products more reliable, easy to use, and better tasting and tolerated.

Individuals requiring enteral nutrition products will welcome a complete pharmacy inventory of products representing a full variety of flavors, attractively merchandised, possibly in a separate department within the pharmacy near other home health care products. Enteral nutrition products are currently displayed haphazardly in many pharmacies' weight control, or "health-food" sections. Such placement may have been acceptable in the past. But times are changing! Enteral nutrition products are neither diet beverages nor health food supplements. They are not fad items. Rather, they are highly professional, balanced nutrition replacement products.

Product manufacturers can be contacted and requested to supply educational and marketing information about their products. This information can be used for self-education, and distribution to patients.

Pharmacists may contact users of

enteral nutrition products, physicians, dietitians, and nursing home administrators personally, and reinforce these contacts through advertising. Willingness to provide a broad assortment of products and auxiliary equipment, desire to assist in product selection, and offer to advise and counsel on nutritional needs, should be emphasized. Manufacturers may also have specific information for pharmacists to use when detailing health care providers.

Counseling Consumers on Enteral Nutrition Products

Pharmacists, by supplying enteral nutrition products, should be alert for signs of malnutrition in persons purchasing them. Visible manifestations of nutrient deficiency include mouth fissures and gum disease, skin breakdown, or weight loss exceeding 10 percent of normal body weight. Such persons should be counseled to seek professional intervention as soon as possible. Conditions predisposing to malnutrition include those listed in Table 2.

If the reason for self-determined supplementing calories or protein in an otherwise healthy person is to assure a balanced nutritional intake, a complete formula product should be recommended. If the reason is to assist the person gain weight after recently experiencing an unexplained weight loss, the individual should be referred to a physician. Such loss may represent serious pathology that requires professional intervention.

Consumers can select from a variety of products that are indicated for similar use, in order to satisfy personal taste considerations. Products such as Vari-Flavors consist of flavor packs that can be added to other enteral formulations to help prevent flavor fatigue. Product manufacturers can also be requested to supply recipes that use enteral nutrition products to create a variety of tasty dishes. These may help reduce the monotony of repeated consumption of single-flavored, or similar-consistency, products. The products generally taste better when cooled. Unopened containers can be stored at room temperature. Unless otherwise instructed, the products are sipped in amounts of 3 to 5 ounces at a time.

Users should carefully wash their hands before opening a container. Container tops should be washed with

Table 2

Risk Factors for Poor Nutritional Status

Dietary History

- Anorexia; poor food intake
- Alcohol abuse
- Chewing or swallowing difficulties
- Fad or restricted diets
- Frequent skipping of meals
- Lack of nutrient intake for 10 or more days

Drug Administration

- Antibiotics
- Anticonvulsants
- Antineoplastic agents
- Oral contraceptives

Medical History

- Cancer
- Circulatory disease
- Chronic disease of GI tract, lung, liver, or kidney
- Coronary artery disease
- Depression
- Diabetes mellitus
- Heart failure
- Hyperlipidemia
- Mental retardation
- Nausea and vomiting, diarrhea
- Neurologic disorders
- Pancreatic insufficiency
- Paralysis
- Surgery involving GI tract
- Recent surgery or illness

Socioeconomic History

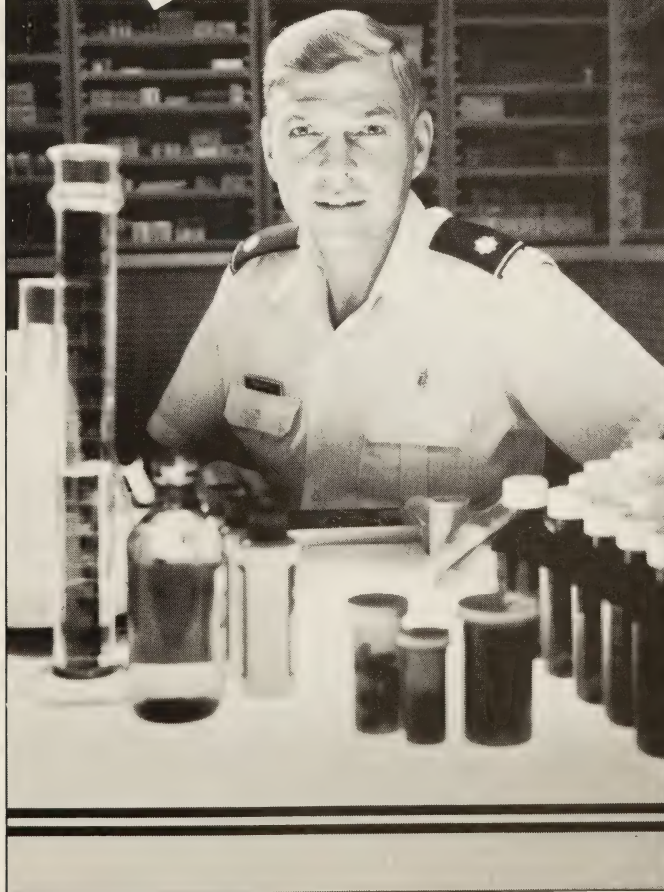
- Elderly, solitary living and eating habits
- Handicap or other infirmities
- Inadequate food budget
- Inadequate food-preparation or storage facilities

water and wiped dry before opening. Enteral nutrition products are sterile until opened, but are excellent media for microbial growth once the seal is broken. When opened, the unused portion of product should be kept refrigerated and used within 24 hours (or longer if so specified on the label).

Those who provide care to patients who receive nutrition through a feeding tube should be instructed on proper maintenance of the equipment. Unless instructed otherwise, a nasogastric tube should be rinsed with water 3 times a day. A pump, if used, should be checked regularly to assure accurate delivery.

There is a support group that emphasizes personal contact with other persons on enteral nutrition. Interested persons can be instructed to contact: The Oley Foundation, 214 Hun Memorial, Albany Medical Center, Albany NY 12208.

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Medicaid's New Prescription Drug Legislation: Prudent Purchasing and Drug Use Review¹

John M. Coster, R.Ph., Ph.D.²

Introduction

As the gavel on the 2nd session of the 101st Congress came down in the early morning hours of October 28th, 1990, a new era in the way that the federal government purchases pharmaceuticals was established. Included in the \$500 billion five-year deficit reduction agreement narrowly passed by the House and the Senate were prudent pharmaceutical purchasing provisions for the Medicaid program that are expected to save \$3.4 billion in tax dollars over five years—\$1.9 for the federal government and \$1.5 for the states. These savings will be achieved by significantly reducing the price that the \$5 billion national Medicaid drug program pays for pharmaceuticals. Medicaid is the 450 billion federal-state health care program for the poor.

The primary Congressional architect of legislation designed to provide a better price to the Medicaid program was Senator David Pryor (D-Ark). Pryor, as Chairman of the Senate Special Committee on Aging, was very disturbed to learn that the Medicaid program, one of the single largest purchasers of prescription drugs in the country, was being denied access to the discounts on pharmaceuticals that other purchasers, such as hospitals and HMOs, routinely received. His objective was to secure these discounts for the Medicaid program. To achieve his intent, Pryor introduced two bills during the Congress—S. 2605, the Pharmaceutical Access and Prudent Purchasing Act, introduced on May 12th; and S. 3029, the Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act, introduced on September 12th.

The first bill required states to form their own prescription drug buying groups or join a federal prescription drug buying group. These groups would act as drug purchasing agents for the Medicaid program, and would solicit bids from drug manufacturers to have their products included on the state's Medicaid drug formulary. This process was structured to emulate the very successful purchasing practices of hospitals and HMOs. The bill was criticized by the Pharmaceutical Manufacturers Association (PMA) and several minority groups as an attempt by Pryor to provide "second class medicine" to the nation's poor. These groups believed that the bill would lead to restrictive formularies which would result in Medicaid patients receiving only the cheapest drug product in each drug class. However, others believed that the PMA was more concerned that the bidding system used in the bill would be employed by other third party prescription plans and HMOs to bargain with the manufacturers over the price of their drugs.

The second bill, S. 3029, was introduced in response to various Medicaid drug discount plans that had been developed by drug manufacturers in the Spring and Fall of 1990, such as the Merck Sharp and Dohme (MSD) Equal Access to Medicines plan. This proposed legislation required manufacturers to offer Medicaid the "best price" for a prescription drug that they charged any purchaser in the marketplace. To assure savings over time and to hedge against manufacturer price increases, the "best price" could increase no faster than the Con-

sumer Price Index-all urban consumers (CPI-U). There was a minimum discount of 10%. State Medicaid programs would be required to cover all drugs for those companies that gave discounts, but states could still use a prior authorization process to encourage appropriate utilization of high-priced or clinically misused products.

Although some contended that the indexing feature in Pryor's second bill was tantamount to price controls on pharmaceuticals, the Congressional Budget Office (CBO) emphasized to congressional staff that long term savings on prescription drugs in the Medicaid program were uncertain unless there was some way to guard against manufacturer price increases. In the final days before passage, even the industry admitted that they would have to live with some form of indexing, and, although pushing hard for the index to be pegged to the CPI-Medical Index (CPI-M), the Congress was not willing to allow drug prices to inflate higher than CPI-U for Medicaid. In general, CPI-U is lower than CPI-M.

A modified form of Pryor's second bill was sponsored in the House by Congressmen Ron Wyden (D-OR) and Jim Cooper (D-TN), both members of the Energy and Commerce Committee, which has jurisdiction over Medicaid. Wyden is also a member of the Subcommittee on Health and the Environment, chaired by Congressman Henry Waxman (D-CA). Waxman saw the drug provisions as a way to find monies to expand Medicaid programs for elderly and children—programs that he believed had been neglected for years. While the original target for savings from pharmaceuticals was \$1.6 billion over five years, the House-Senate reconciliation conference agreed to increase that amount to \$1.9 billion to pay for some of the Medicaid expansions.

Impact on the Pharmaceutical Industry

Beginning January 1, 1991, pharmaceutical manufacturers are required to give the Medicaid program a specific schedule of rebates as a condition of coverage of their prescription drug products. For manufacturers of single-source (such as AZT, Seldane) and innovator multiple-source drug products (such as Valium, Motrin), there is a minimum rebate of 12½% off the Average Manufacturer's Price (AMP) for 1991 and 1992, with the minimum rebate increasing to 15% in 1993 and beyond. Manufacturers would have to give Medicaid, however, the higher of this minimum rebate or the difference between the AMP and the manufacturer's "best price" for that product. The AMP is the price that manufacturers charge wholesalers to buy their products.

In the legislation, "best price" includes those prices that manufacturers offer to hospitals, HMOs, and certain components of the Department of Veterans' Affairs (DVA), and are to be determined regardless of manufacturer's packaging, such as unit dose products. The definition of "best price" excludes DVA depot drug prices and single award contracts (such as the contract

that the DVA currently has with a major supplier of IV solutions) and "nominal" prices offered to charitable groups or organizations. These exemptions were made for several reasons. Federal government depot prices reflect the manufacturer's costs of delivering the product in bulk to a provider, without packaging costs. The provider, such as the DVA, then assumes the costs of repackaging and shipping to individual outlets. Medicaid is a reimbursement system, not a direct purchaser of drugs, so it seemed unfair for Medicaid to have access to prices that are determined based on this mode of distribution. DVA Federal Supply Schedule (FSS) prices are not excluded from consideration. In addition, Congress did not want to threaten the prices that charitable organizations and clinics such as "Planned Parenthood" pay for drugs, such as the pennies a pack paid for birth control pills, and therefore excluded them from the definition.

An "additional rebate" will recover any increase in the average manufacturer prices over the rate of inflation, as measured by the Consumer Price Index-all urban consumers (CPI-U). The additional rebate is calculated on an individual drug basis for the first three years, and then switches to a system of aggregation in 1994.

Drug manufacturers have significant incentives to participate in the Medicaid rebate program since there will be no federal Medicaid matching funds available for the drugs of those manufacturers that have not entered into a rebate agreement. However, manufacturers that have rebate agreements in effect will have all their products covered by the state Medicaid programs. This is a particularly significant victory for the drug companies since many state Medicaid programs do not cover all drug products of all manufacturers for both cost and patient care reasons. In addition, there is usually a significant lag time between the marketing of a new drug and coverage by a state Medicaid program. Now, all new drugs will have to be covered immediately by a state Medicaid program for a period of not less than six months after approval. All these benefits will have significant "spill-over" effects for the prescribing of a drug company's products by physicians in other sectors of the ambulatory care market.

Congress developed different rebate amounts for generic drug products: the rebates will be 10% off the AMP in 1991-1993, and 11% off the AMP thereafter, with no indexing provisions. These rebates are different from the rebates for the single-source and innovator multiple-source products because the generic industry has more competitive prices and generic companies operate on much smaller profit margins than do the brand name companies.

Relief for the States

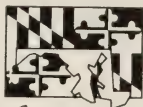
A major objective of the legislation was to provide financial relief to the state Medicaid programs that were

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having trouble making ends meet in their prescription drug program. It is projected that states will save \$1.4 billion on drugs costs over the next five years as a result of the legislation. The states do, however, incur some additional responsibilities under the legislation relating to coverage of prescription drug products.

One of the major issues discussed during the debate was Medicaid beneficiaries' access to prescription medications. The manufacturers argued that states were unnecessarily and artificially restricting Medicaid patients' access to drugs for cost reasons, especially new products. The states argued that they could not afford placing new, expensive drugs on their formulary while they already covered drugs that they thought were as good, and less expensive, than new alternatives. The PMA saw the legislation as an opportunity to eliminate, through federal legislation, their number one nemesis in state Medicaid programs: drug formularies. In the end, however, the drug companies were only partially successful in their effort.

The compromise requires states to cover single-source drugs and innovator multiple-source drugs (when a restrictive prescription has been issued) only if the drug's manufacturer has entered into an acceptable rebate agreement with the Secretary of Health and Human Services. The drugs of manufacturers not providing an acceptable rebate WILL NOT be eligible for federal matching funds UNLESS the drug has been designated a "1-A" drug by the FDA and the Secretary has approved the state's determination that the drug is "medically necessary" for the state's Medicaid population.

To address the industry's concern that Medicaid patients arbitrarily would be denied access to new, breakthrough drug products, state Medicaid programs have to cover new drugs for a period of six months after approval, after which time the program may place the drug on prior approval. Prior approval requires the prescriber to obtain "permission" to use the drug from the Medicaid program before it can be prescribed. The law allows the states to place all drugs on prior approval, and there are a limited number of drug classes that states, at their option, may exclude from coverage for Medicaid patients, even if subject to a rebate agreement, such as drugs to promote fertility or hair growth.

The bottom line for the state Medicaid programs is that they are likely to save millions of dollars each year on prescription drug costs, which should allow them to remove some of the restrictions that have had to be implemented to control costs, such as limits on the number of prescriptions that a Medicaid patient can have dispensed each month.

Impact on Pharmacy Providers Medicaid Reimbursement Reform

Pharmacy providers are likely to be as relieved as the states that the manufacturers will be participating in

cost containment by giving rebates to Medicaid. Like many other members of Congress, Senator Pryor strongly believes that pharmacists have been targeted by HCFA as the exclusive focus of drug program cost containment efforts in Medicaid—efforts that were unsuccessful because the pharmacist had no control over the cause of the problem: manufacturer price increases.

Senator Pryor made Medicaid pharmacy reimbursement reform a major policy objective of the legislation. His original bill, S. 2605, restructured the Medicaid reimbursement system, basing reimbursement on the competitive nature of the pharmacy marketplace. Reimbursement would have been pegged at the pharmacist's usual and customary charge, capped at 90% of state-wide actual charges for that prescription. The theory was that the competition that exists among pharmacists in the retail marketplace would result in lower prices being passed on to state Medicaid programs.

However, Pryor's reimbursement reforms came under sharp attack from HCFA, the state Medicaid programs, and pharmaceutical manufacturers. These groups argued that the reform was inflationary, and would negate any program savings achieved under the manufacturer rebate system. Manufacturers charged that the potential increase in payments to pharmacists made under the system was analogous to "robbing Peter (the manufacturers) to overpay Paul (the pharmacists)." In addition, the trend in health care policy reimbursement over the last decade has backpeddled from charge-based reimbursement. Policy makers feared that other providers would also demand charge-based reimbursement if pharmacists were successful in their quest. Pryor, however, had data from a large outpatient prescription drug program that refuted these assertions.

In the second bill, however, Pryor tried to allay the fears of state Medicaid directors worried about the financial impact of a charge-based reimbursement system. He introduced a provision that would provide for a 5% set aside as a restitution payment for pharmacists for what he characterized as a decade of unfair reimbursement cuts. That is, states would have to set aside 5% of the rebates they received from the manufacturers and provide this back to pharmacists in a lump sum payment in proportion to the number of Medicaid prescriptions that they dispensed. The bill also provided for a two-year moratorium on any changes by the states or HCFA in reimbursement levels to pharmacists for those states that were in compliance with the reimbursement regulations.

When the final package was crafted, conferees decided to drop the set aside and extend the moratorium on reimbursement reductions to four years, beginning January 1, 1991. The sense was that the development of a set aside would be a poor policy precedent since other health care providers might want similar provisions enacted for them. In the end, the four-year moratorium

may well provide greater financial restoration to pharmacists than a set aside. The moratorium will prevent HCFA and the states from focusing drug program cost containment efforts on pharmacists and will give states sufficient time to study whether current pharmacy reimbursement rates are adequate. To make this determination, the Secretary is required to conduct a study of states' Medicaid pharmacy reimbursement rates, including dispensing fees.

Pharmacists' Counseling and Drug Use Review Provisions

The new Medicaid law contains several provisions that have the potential to significantly improve the prescribing and dispensing of drugs to Medicaid patients. The legislation establishes a comprehensive program of drug use review with a prospective component, which consists primarily of pharmacists' counseling patients on drug use, and a retrospective component, which is designed to identify and correct long term patterns of inappropriate drug use.

With respect to the prospective component, the Congress recognized the professional skills and training of pharmacists by adopting language that asks pharmacists to review the appropriateness of drug therapy at the point of dispensing, and to counsel Medicaid patients on the use of their medications. Pharmacists are expected to collect and record drug-related information about the patient and check new or refill prescriptions for drug interactions or adverse drug reactions.

The provisions related to counseling ask pharmacists to offer to talk to patients about how to take their medications. The patient counseling guidelines in the bill reflect the national standards adopted by the National Association of Boards of Pharmacy (NABP) in 1990. NABP and the major pharmacy practitioner organizations, APhA and NARD, were strong supporters of these provisions, recognizing that the profession needed to send strong signals to Congress concerning its role in protecting and enhancing public health.

Pharmacists should be assisted in fulfilling their counseling responsibilities to Medicaid patients as a result of two demonstration projects that are mandated under the law. The first requires the Secretary to complete a multi-site demonstration study by January 1, 1995, of the cost-effectiveness of paying pharmacists for cognitive or clinical services, including reimbursing a pharmacist for not dispensing a drug when there is potential for an adverse drug effect. In the other study, the Secretary must conduct a ten-state demonstration project of the effectiveness of providing information through an electronic claims transfer system about a patient's drug and medical history that will assist pharmacists in fulfilling drug therapy screening and patient counseling requirements. Information would be captured in a central repository of information so the pharmacist would have a patient's complete medication

profile that would assist in detecting adverse reactions and therapeutic duplications.

State Medicaid programs are currently required to have a program to identify patterns of fraud and abuse in the prescription drug program, such as detecting overprescribing and overdosing of controlled substances. Under the new law, states will be required to develop a program of retrospective utilization review and educational outreach targeted at improving the drug prescribing and dispensing practices of health professionals. Prescription drug data for this purpose will be collected and compiled from the claims data submitted by pharmacies. The data would then be analyzed by state drug use review boards, established to oversee the operation of the state's entire DUR program. To insure that the retrospective program focuses on improving therapeutic outcomes, one-third of the members of the board must be practicing pharmacists, and one-third must be practicing physicians. The DUR board is also responsible for designing educational interventions for health professionals, which may include mailings, face-to-face meetings, or educational conferences or symposiums.

Pharmacy stands to gain both in economic and professional terms under the bill. No other providers have enjoyed a four-year moratorium on reimbursement reductions in a third party health care program. In addition, the demonstration projects should help pharmacists firmly establish their role in the health care system as more than just dispensers of medications.

Conclusion

In 1991, the relationship between the pharmaceutical industry and the federal government begins a profound change. As Senator Pryor said on the floor of the Senate many times, in the past the federal government and the state Medicaid programs have essentially "paid what the drug manufacturers have asked for." In 1990, Congress recognized that it was squandering an opportunity to use its tremendous purchasing power for prescription drugs to obtain a better deal from the manufacturers. Now, Congress has mandated that state Medicaid programs pay a fair price for drugs and there is tremendous opportunity to improve the drug use patterns in a population of individuals known for taking a large number of medications—the poor and elderly.

¹ Prepared for the Center on Drugs and Public Policy, University of Maryland Graduate School, Baltimore.

² United States Senate Special Committee on Aging, Washington, D.C.

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Gallup Poll Shows Strong Public Interest in Nutritionals With Medical Benefits

A recent public opinion poll conducted by The Gallup Organization shows strong public interest in food and nutritional products that may contribute to the treatment or prevention of disease. The independent study, sponsored by the Foundation for Innovation in Medicine, was based on telephone interviews conducted in mid-November, 1990 with a national sample of 1,013 adults, 18 years of age and older, and is considered accurate within a plus or minus 3 percent margin of error.

According to the Gallup survey, Americans place considerable importance on having accurate and sufficient information on the medical benefits of foods and nutritional products. Of those interviewed, 53 percent ranked this information as very important, with an additional 31 percent calling it fairly important. Only 12 percent said it was not too important and 4 percent said it was not at all important.

When asked if they receive accurate and sufficient information about foods and nutritional products that may treat or prevent disease, 19 percent agreed completely and 50 percent mostly agreed. Nineteen percent mostly disagreed and 10 percent disagreed completely.

This subject has been the focus of considerable attention during the past year, culminating in the passage of the Nutrition Labeling and Education Act in October, 1990. This law will require a number of nutrients to be listed on the labeling for packaged foods, fruits, vegetables and raw seafood, and will permit

manufacturers to make health claims in a very few specific instances which are well established in public domain scientific literature. No method was created, however, for companies to submit scientific evidence for countless additional nutrients and potential new health claims.

A substantial majority (92 percent) believe that companies should be encouraged to conduct research for advances in foods and nutritional products which prevent and cure disease, with a total of 60 percent agreeing completely and 32 percent mostly agreeing. A small number (2 percent) mostly disagreed and 4 percent disagreed completely.

Twenty-seven percent agreed completely and 36 percent mostly agreed that existing government regulations encourage companies to conduct research for advances in foods and nutritional products which prevent or cure disease. Twenty percent mostly disagreed and 10 percent disagreed completely that current regulations encourage research in this area.

Here is yet another example where the public is not well informed on a critical health issue. In fact, the current regulatory structure discourages research for nutrition-related health advances. Not only does it fail to provide an appropriate means for review and approval of new discoveries and developments, but it fails to provide exclusive product rights necessary to support companies which make the investment needed for the responsible re-

search and development of new products and health claims.

A very high percentage of those interviewed (86 percent) said that they believe nutritional products could be used to enhance the effectiveness of pharmaceutical and other medical therapy, while only 6 percent disagreed and 8 percent said they did not know.

An explosive number of clinical studies are being published in medical journals and reported by mass media, showing a dramatic range of potential medical benefits for a growing array of nutritional substances. Definitive studies are necessary to confirm these findings and develop new products, however, and this will require a significant investment in research and development, proper incentive for private funding and an appropriate means of government review and approval. In the research-based pharmaceutical industry, where such conditions exist, investment in research and development now exceeds that of the National Institutes of Health.

A large majority (84 percent) said they favor government regulations that would facilitate and insure accurate and sufficient information from companies on the medical benefits of foods and nutritional products, with only 11 percent opposed and 5 percent had no opinion. Sixty-one percent said they strongly favor such regulations, and 6 percent said they were strongly opposed.

While the Nutrition Education and Labeling Act responds in part to

GALLUP SURVEY

Would you favor or oppose government regulations which encourage scientific research for advances in foods and nutritional products which help prevent or cure disease?

Favor



87%

Oppose



10%

Do you favor or oppose government regulations that would facilitate and insure accurate and sufficient information from companies on the medical benefits of foods and nutritional products?

Favor



84%

Oppose



11%

this public interest, its net effect is the opposite. Its focus is restricted to the listing of a small number of the many nutrients found in foods, and permits health claims only in a few cases which are currently well established in public domain scientific literature. No provision is made for the development, review and approval of new health claims based on proprietary research.

An even larger majority of 87 percent said they favor government regulations that would encourage research for advances in foods and nu-

tritional products which help prevent or cure disease. Only 10 percent were opposed and 3 percent had no opinion. Sixty-eight percent said they strongly favor such regulations, and 5 percent said they were strongly opposed.

Again the net effect of the Nutritional Education and Labeling Act is the opposite of public opinion. Not only does it fail to provide an avenue for review and approval of new scientific developments, but it fails to provide exclusive product rights to

companies which make the research investment essential for the responsible development and availability of such advances.

When asked about their awareness of government regulations that affect research and information on the medical benefits of foods and nutritional products, only 7 percent said that they were very aware and 46 percent said they were fairly aware. Thirty-nine percent said they were not too aware, and 7 percent said they were not at all aware.

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The Nutraceutical Revolution

Overview

Nutritional products with disease related benefits—from diets, dietary supplements and isolated natural substances to genetically engineered designer foods—are rapidly becoming part of mainstream medicine as well as a focus of consumer interest. The result is the “nutraceutical” revolution, in which such products are increasingly developed and recognized for their medical value.

In order for this new field to reach its full potential, however, it must be science-based and proper information should be delivered to both physicians and the public. Just as a responsible, regulated industry has been established for pharmaceuticals, a research-based industry is also needed for nutritional products with medical benefits. Unfortunately, the existing U.S. regulatory structure fails to provide appropriate procedures for the development and approval of nutraceuticals, and actually discourages research investment and the dissemination of health information relating to products in this area.

At the heart of the problem is the fact that current regulations are designed to cover either foods or drugs—but nothing in between. For nutraceuticals, which fall into a gray area between these two categories, there is currently no separate system for regulatory compliance. The Nutrition Labeling and Education Act recently approved by Congress, for example, focuses almost exclusively on general food labeling. As such, it provides no mechanism for exclusive marketing rights to provide the necessary incentive for investment in the research and development of new products with specific health benefits. Furthermore, it fails to provide for the development of health claims tailored for specific product advances. At the other end of the spectrum, existing drug regulations require rigorous and costly safety and efficacy

testing which in most cases is inappropriate for nutritional products.

The obvious solution is to update the regulatory process to adequately and appropriately address nutraceuticals. The goal should be to encourage rather than discourage a research-oriented approach to the development and marketing of nutritional products with health benefits. This can be accomplished by creating a regulatory system for nutraceuticals which diminishes the administrative barriers and financial risks for the research and development of important product innovations, and facilitates the development of exclusive and responsible health claims by individual corporations.

Review of Existing Regulations

Current food and drug regulations present a Catch-22 situation for nutritional products with health benefits.

Claims about nutrients usually trigger a requirement for nutrition labeling. U.S. Food and Drug Administration (FDA) regulations, however, state that any food with nutritional labeling will be deemed misbranded if it represents or implies that it is effective in the prevention, cure, mitigation or treatment of any disease or symptom.

Moreover, if a product is properly labeled as a food but independently promoted to show that it will help cure, treat, prevent or mitigate disease, it then falls under the realm of drug regulations and is illegal unless in compliance with all federal requirements for drugs. The current research and development cost for a New Drug Application (NDA), which must be reviewed and approved by FDA prior to marketing, typically exceeds \$200 million and requires ten years or longer from the start of preclinical testing to final approval. Further requirements include drug registration, drug listing,

and compliance with pharmaceutical Good Manufacturing Practices.

Another possible classification is as a food additive, which is defined as a food ingredient that is not generally recognized as safe for its intended use. Testing requirements for this classification can be almost as rigorous as for a new drug.

An additional product category which has been accepted by FDA is that of “medical foods.” A medical food is a product intended for use under medical supervision to provide essential nutrition in the context of some disease or symptom. Examples include post-surgical feeding solutions, diabetic foods and hypoallergenic foods. Such products are only promoted to medical professionals for essential nutrition, and need only comply with food requirements.

Within the context of these existing product classifications, however, paradoxes and inconsistencies abound.

In 1984, for example, the FDA implemented a so-called sodium initiative, in which it developed definitions for low-sodium foods and encouraged food processors to develop and market them because of the recognized effect of sodium on high blood pressure. At the same time, however, the FDA would not permit food processors to tell consumers why they should consume low sodium foods—since the foods were not classified, tested and approved as drugs. This was a distinct disadvantage for the sodium initiative, since the low-sodium foods often did not taste as good as traditional products and the health benefit of low sodium could not be communicated. Food companies were left with the commercially infeasible task of trying to market foods that did not taste good without being able to promote their redeeming health benefits.

On the other hand, despite legal and regulatory positions to the con-



Potential medical benefits from an expanding array of nutrients are being identified in clinical studies.

trary, the promotion of health claims for foods has now become widespread. According to data published in 1990 in the *New York Times*, 40 percent of all new food products introduced during the first half of 1989 included general or specific health claims, and a third of the \$3.6 billion spent annually for food advertising now presents some form of health message.

A turning point may have occurred in the late 1960's and early 1970's, when the FDA sought to encourage breakfast cereal manufacturers to emphasize nutrition, rather than sugar and prizes for children, in their promotional activities. Since that era, the cereal industry has

leapfrogged the FDA and now places its primary promotional emphasis on nutrition. At the same time, this promotional emphasis on the health benefits of cereals has broadened to encompass a multitude of food products in many categories—with virtually no direct challenge from the FDA.

In order to regain FDA control of the plethora of health claims for food products, Congress recently passed new legislation for general food labeling which disallows health claims except in a few situations where they are well supported by publicly available scientific evidence. Claims considered allowable include the role of dietary fiber and

low fats in the prevention of colon cancer and heart disease, sodium as a contributor to high blood pressure, and calcium to help prevent osteoporosis.

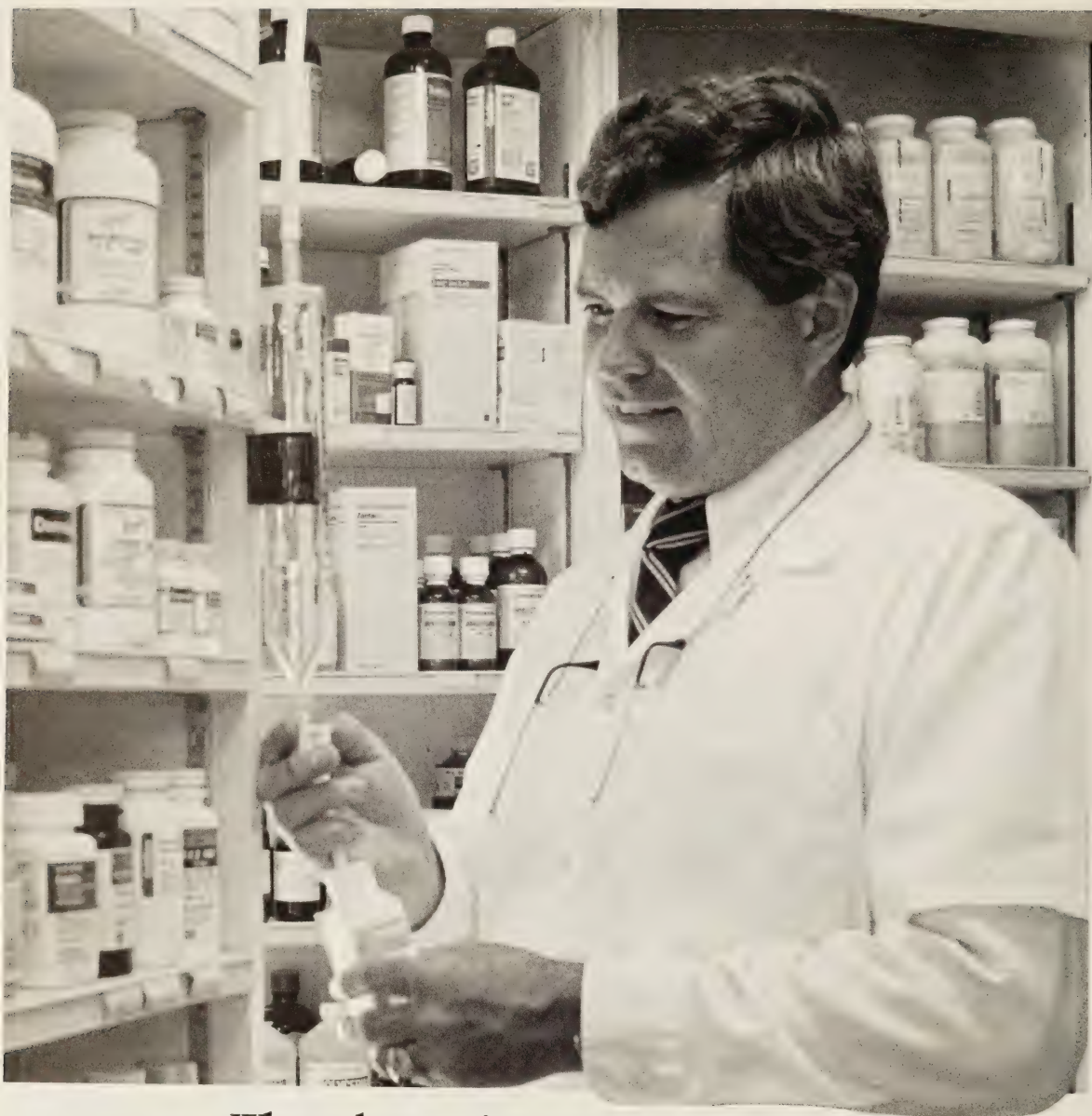
The new legislation essentially legalizes current promotional practices in selected instances for general food categories, while ignoring the importance of nutritional supplements and the potential for significant medical and scientific advances. Unlike regulations for pharmaceuticals, no mechanism was proposed to permit exclusive health claims for nutritional products based on proprietary research. This, in effect, removes any financial incentive for private companies to invest in the research and development of innovative nutritional products and product uses.

Moreover, in the absence of research-based health claims developed for specific products, nutritional information reaching the public lacks balance and accuracy. Because specific claims are not developed, nutritional information is dominated by press interpretations of nonproprietary scientific studies and a profusion of health-related messages for general food categories. In the face of this confusion, it seems evident that both physicians and large segments of the public would appreciate more detailed and balanced information on the role of nutrition in the prevention and treatment of disease.

At present there is no avenue for submitting a new nutritional product with medical value to the FDA short of classifying it as a drug and filing an NDA, at a cost of many millions of dollars and years of testing and evaluation. Even if approved as a drug, however, a company's exclusive marketing rights for a nutraceutical are uncertain at best.

Proposed Solution

The nutraceutical revolution has arrived worldwide and cannot be stopped. For the first time in medicine, doctors have joined consumers in believing that nutrients have medical value. This movement will only



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gain momentum as knowledge of disease processes continues to advance, and new means of product innovation and mass production continue to unfold through biotechnology and other scientific resources.

In the past there was the health food industry, a consumer business largely based on traditional home remedies. Then calcium, fiber and fish oil came along—with clinical data to back them up. In effect, the product managers in this business were the National Institutes of Health and academic medicine, who had conducted clinical studies and presented suggestive scientific information. The marketing and sales force were the mass media, who publicized and dramatized it. And the customers were the physicians and consumers, who increasingly bought it.

This phenomenon has been possible because the FDA does not regulate scientists, or the media, or physicians and consumers. It only regulates industry, which has neither conducted the research nor in most cases made the claims. In other words, there is no regulatory system for the nutraceutical movement—despite the fact that it has entered the mainstream of science, medicine and the consumer marketplace.

What is a science-based company to do if it wishes to participate in the nutraceutical revolution? As of now, no practical and legal approach is available—which bodes poorly for progress in this area.

The obvious solution is to establish an updated regulatory process which serves the public interest and matches today's scientific and medical reality. Instead of discouraging private research investment for the development of innovative products and responsible claims, a new system must be established which encourages a vital research-oriented industry for the development and marketing of nutraceuticals.

Because of the FDA's difficulties in regulating nutrition through traditional food and drug guidelines and

regulations, The Foundation for Innovation in Medicine has proposed that a Nutraceutical Commission be established specifically for the regulation of this new product category.

The new commission should preside over a well conceived system designed to bring nutraceuticals into the mainstream of the food and health care industries. The new system should diminish the present barriers and risks for private research and development, encourage research by conferring a degree of exclusivity on nutraceutical products, and facilitate and regulate the development of responsible promotional claims.

In order to promote an appropriate level of research for nutritional products and create the exclusivity necessary to attract commercial investment, the Orphan Drug Act might be used as a model. Under the Orphan Drug system, designed to promote pharmaceutical innovations for rare diseases, a company may be permitted to conduct fewer clinical studies and may be granted exclusive marketing rights for seven years after approval.

Since nutritional products do not pose the same potential risks as new drug compounds, the cost of research might be further reduced by omitting preclinical testing requirements, such as the IND (Investigative New Drug application) process mandated for pharmaceuticals. In the case of nutraceuticals, clinical investigators themselves might serve as the initial clinical subjects.

As an additional streamlining measure, in reviewing products for approval the new commission might operate on a case-by-case basis, similar to a court system, rather than through general formal guidelines, which experience has found are difficult to formulate in the area of nutrition.

A regulatory process for nutraceuticals would fill a void not only for the research-based pharmaceutical industry, but for growing segments of the food industry as well. The National Cancer Institute, for

example, is now funding research for the development of designer foods with cancer prevention potential through the use of biotechnology. Food science departments of major universities are increasingly becoming authorities on the health-related components of every-day foods. This activity could be further enhanced through block grants from the National Institutes of Health for the clinical testing of nutraceuticals. What is missing, however, is a mechanism for their development into commercial products with specific health claims.

As an alternative to creating a new commission for nutraceuticals, options also exist for developing a regulatory process for nutraceuticals within the existing framework of the FDA.

Streamlined testing and approval requirements could be developed within FDA specifically for this new classification. In order to allow companies to maintain a proprietary advantage from their research investment, the FDA might permit private studies to be held confidential, rather than limiting scientific evidence to publicly available data. Product labeling for specific health claims might in turn be negotiated on an individual basis, in the same manner pharmaceutical labeling is now negotiated with the FDA Drug Center.

Conclusion

Regardless of the form it might take, new regulatory procedures are needed to accommodate the growing array of new products and developments that fall outside the traditional concept of either a food or a drug. In order to be effective and to serve the best interest of the public, this new process should be designed to foster rather than discourage scientific research, encourage the commercial development and availability of important advances, and facilitate the communication of accurate and complete information on nutraceutical products with specific health benefits.

Nutraceuticals in Limbo

Following are some examples of the growing array of nutrients and corresponding disease-related benefits which have been demonstrated in clinical studies. Unfortunately, existing regulations fail to foster definitive research and lack an appropriate means of approval for compounds which do not fit the traditional concept of either a food or a drug.

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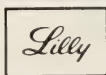
<u>Nutraceutical</u>	<u>Disease-related Benefit</u>	<u>Status</u>
niacin	Reduction of recurrent myocardial infarctions.	Studies published. ¹ No development of studies for approved health claims.
calcium	Treatment and prevention of osteoporosis, cancer, hypertension.	Major studies pending publication. ² No development of studies for approved health claims.
vitamin A	Treatment and prevention of measles.	Major study published. ⁵ No development of studies for approved health claims.
beta carotene	Prevention of lung cancer.	Major studies published. ⁴ No development of studies for approved health claims.
fish oil	Treatment and prevention of hypertension.	Studies published. ⁵ No development of studies for approved health claims.
pyridoxine	Treatment and prevention of depression.	Studies published. ⁶ No development of studies for approved health claims.
magnesium	Treatment and prevention of diabetic hypertension.	Studies published. ⁷ No development of studies for approved health claims.
phyto-chemicals	Cancer prevention.	National Cancer Institute program underway to develop foods with enhanced concentrations.
garlic	Reduction of arteriosclerosis.	Studies published. ⁸ No development of studies for approved health claims.
ubiquinones	Reduction of damage from myocardial infarction.	Studies published. ⁹ No development of studies for approved health claims.

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1991 Tax Dates

The following are due dates for federal and state taxes that will most likely affect you or your organization. Taxes that are due four or more times during the year are identified by abbreviations explained below the chart

JANUARY 1991		JUNE 1991	
January 4	FD(a)	June 5	FD(a)
January 15	FD(b), FI/SI	June 17	FD(b), FC, SC, FI/SI
January 22	ST	June 21	ST
January 31	FQ, FU, FD(c), SQ, SU Employees' statements W-2 for amounts withheld in 1990 to be furnished by employer. Employer file federal unemployment tax Form 940 for 1990.		
FEBRUARY 1991		JULY 1991	
February 5	FD(a)	July 3	FD(a)
February 15	FD(b)	July 15	FD(b)
February 21	ST	July 22	ST
February 28	Forms W-2 "A" copies with transmittal form W-3 filed with Social Security Administration.	July 31	FQ, FU, FD(c), SQ, SU
MARCH 1991		AUGUST 1991	
March 5	FD(a)	August 5	FD(a)
March 15	FD(b) Federal and state corporate income tax return due or you must pay estimated amount due and file for automatic 6 month extension. Interest will be paid on amount paid after March 15.	August 15	FD(b) Last day for filing tax return or obtaining additional 2 month extension by individuals who obtained an automatic 4 month extension.
March 21	ST	August 21	ST
APRIL 1991		SEPTEMBER 1991	
April 3	FD(a)	September 5	FD(a)
April 15	FD(b), FC, FI/SI, SC Federal and state individual income tax due or you must pay estimated amount due and file for an automatic 4 month extension. Interest will be paid after April 15. State personal property tax due.	September 16	FD(b), FC, FI/SI, SC Last day for filing tax return by calendar corporations that obtained an automatic 6 month extension.
April 22	ST	September 23	ST
April 30	FQ, FU, FD(c), SQ, SU	OCTOBER 1991	
MAY 1991		October 3	FD(a)
May 3	FD(a)	October 15	FD(b)
May 15	FD(b)		Last day for filing tax return by individuals who obtained 2 month extension in August.
May 21	ST	October 21	ST
		October 31	FQ, FU, FD(c), SQ, SU
		NOVEMBER 1991	
		November 5	FD(a)
		November 15	FD(b)
		November 21	ST
		DECEMBER 1991	
		December 4	FD(a)
		December 16	FD(b), FC, SC
		December 23	ST
FD(a)-	Last payment due on federal income and social security taxes withheld during the previous month if over \$3,000 was withheld. You are required to deposit to deposit the amount withheld within 3 banking days after you reach \$3,000 at the end of any eighth-monthly period (these periods end on the 3rd, 7th, 11th, 15th, 19th, 22nd, 25th and last day of the month).	FC-	Federal estimated corporation taxes must be paid if on calendar basis (note—fiscal year corporations pay this tax on 15th day of 4th, 6th, 9th, 12th, month of their year).
		FI/SI-	Federal and state estimated individual tax for previous quarter due.
		FD(c)-	Federal social security tax and withholding tax due on domestic workers.
FD(b)-	Federal income and social security taxes withheld must be deposited by this date if between \$500 and \$3,000 was withheld during the previous month. Earlier deposit is required when \$3,000 is reached prior to this date.	ST-	Maryland state sales tax due.
		SQ-	Maryland state income tax withheld due for previous quarter.
FQ-	Federal quarterly income and social security taxes withheld must be paid.	S-	Maryland state unemployment taxes due.
FU-	Federal unemployment tax must be paid.	SC-	Maryland state estimate of corporation tax due.

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Community Forum

Investing for Today

Financing Your Children's Education: Have You Done Your Homework?

Daniel K. Hays

Whether you have tots or teens, planning for their education can be a worry, especially when you consider the facts.

Startling Statistics

In the last 10 years, the increase in college costs has outstripped inflation by two percentage points each year.

This means that in the next year, the average student will pay 7% more for tuition and costs. At that rate, a four-year degree at a public college or university will cost nearly \$50,000 by the year 2000, and the same degree at a private university could reach the \$160,000 mark.

Suppose you want to accumulate \$50,000 by the year 2000. You would have to invest \$3,618 a year for the next 10 years (assuming a 7% after-tax rate). If you delay starting to save until 1993, you would have to set aside \$5,777 a year. To accumulate \$160,000 by the year 2000, assuming the same after-tax rate, you would have to invest \$11,580 a year for the next 10 years. And if you wait until 1993 to begin saving, the amount needed jumps to \$18,488 per year.

Custodial Accounts Affected

To make matters worse, tax reform negatively impacted the most common tax-advantaged methods of saving for college: custodial accounts established under the Uniform Gifts to Minors Act and Clifford trusts. While the maximum contribution to a custodial account remains at \$10,000 per person per year without incurring gift taxes, the taxes on earnings have changed. Under the new laws, children under the age of 14 are taxed at their parents' presumably higher rate if they have unearned income over \$1,000. For children under 14 years of age, the first \$500 of unearned in-

come counts as a standard deduction and the second \$500 is taxable at the 15% rate. Children over the age of 14 are taxed at their own tax bracket.

Clearly, the importance of planning ahead cannot be overemphasized whether you're just starting a college savings plan or are already meeting tuition payments.

Depending on your tax bracket and the age of your children, there are a number of investments to consider.

Tax-Advantaged Alternatives

Income generated for children younger than age 14 in custodial college fund accounts should include tax-exempt and tax-deferred securities.

Zero-Coupon municipal bonds are well-suited to saving for college because they allow for accurate planning of expenses. Zeroes purchased at a deep discount from face value and a maturity date that coincides with the time your child is ready for college can appreciate in value tax-free, assuring that the money will be available when you need it.

DINTS (Deferred Interest Securities) are a select group of corporate zero coupon bonds that defer tax liability until the issues are sold, called or mature. DINTS compound tax-deferred so the eventual taxes will probably be paid at the child's lower tax bracket, resulting in a higher after-tax yield.

Taxable Investments

For investors who are less concerned about tax ramifications, the following instruments may be of interest.

STRIPS (Separate Trading of Registered Interest and Principal Securities) are component parts of United States Treasury notes and bonds that sell at a discount from

face value and pay only principal at maturity. These issues are available every three months up to 30 years, which means you can create a lump sum payment that would mature all at once or you could stagger maturities to provide periodic distributions for education expenses. Treasuries by themselves may be another option to consider.

Growth-oriented mutual funds and unit trust investments are worth considering if your resources are limited. Both alternatives offer the benefits of investing in diversified portfolios to reduce risk, the opportunity to compound reinvested earnings and the ability to set up an investment that pays a specific income on a regular basis.

Stock investments may be your choice if you have time to save and prefer an aggressive strategy aimed at capital appreciation.

Certificates of Deposit or other conservative fixed-income vehicles are appropriate if you're faced with college tuitions within the next year or two.

Another Alternative

Suppose your child is ready to enter college immediately. You've been putting money away but you're still short of funds to meet tuition payments. A home equity loan is an inexpensive way to borrow money. Rates are generally low, your loan is secured by your mortgage, and the funds you borrow are tax deductible when used for education purposes.

To complete your homework on ways to fund your children's education, consult your financial adviser. He or she can help you determine the best method of meeting your objective.

So . . . seize the day!

Daniel K. Hays is a financial consultant with Advest, Inc. in Lutherville, Maryland. If you have any questions, he can be reached at 800/272-7368.

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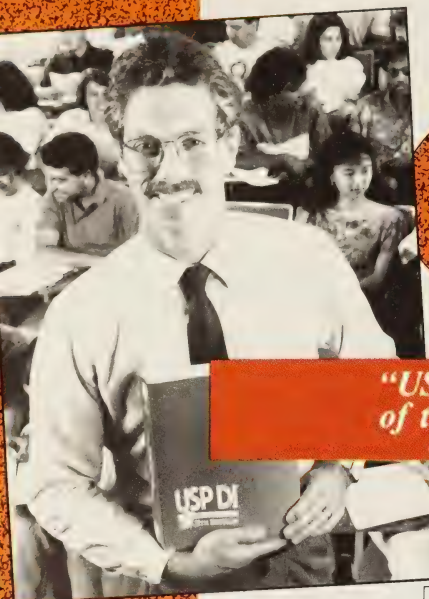
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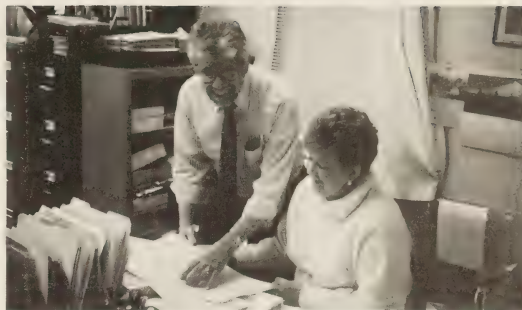
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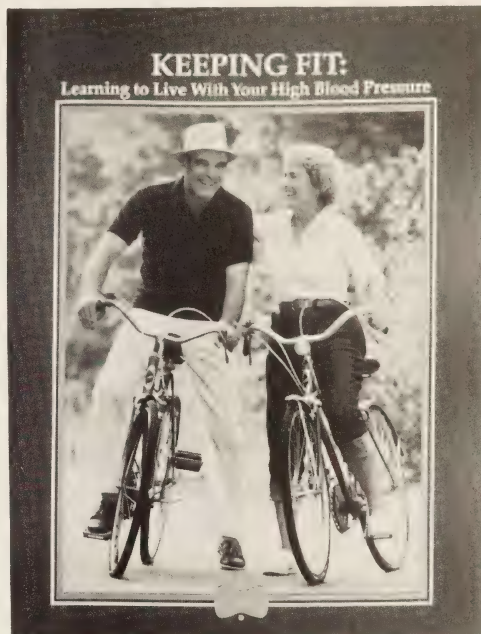
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Manning the MPhA Drug Utilization Review Program are Dr. Richard Baylis and his assistant Donna Clatchey.



The faces behind the phones! The staff hard at work for the MPhA membership talk to many of you without ever having the opportunity to meet you face to face. This is Maribeth Porter, MPhA secretary and CECC coordinator.



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The Maryland Pharmacist **APRIL 1991**

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by July 1, 1991. A continuing education certificate for one contact credit will be mailed to you within 30 days. Please type or print clearly.

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How long did it take you to complete the program? _____ minutes

Enteral Nutrition Products

1. The body stores excess supplies of all of the following EXCEPT:
 - a. carbohydrates.
 - b. fat.
 - c. protein.
 - d. vitamins/minerals.
2. According to information in the article, the most important difference between TEN and TPN is:
 - a. TEN is administered intravenously; TPN is given orally.
 - b. TEN is used for patients with dysphagia.
 - c. TEN is much more effective than TPN.
 - d. TPN delivers nutrients by means of a tube to the stomach.
3. All of the following are "modular" products that contain high amounts of either carbohydrate, fat, or protein and are used to provide specific dietary requirements EXCEPT:
 - a. Modulac.
 - b. Casec.
 - c. MCT.
 - d. Pulmocare.
4. The most important energy source for humans is:
 - a. carbohydrates.
 - b. fat.
 - c. protein.
 - d. vitamins/minerals.
5. The storage component in the body that serves as a large reservoir for the energy source referred to in question #4 above is:
 - a. adipose tissue.
 - b. glycogen.
 - c. gallbladder.
 - d. steroids.
6. A request for a predigested or hydrolyzed formula should be filled by dispensing:
 - a. Isotein HN.
 - b. Ensure Plus.
 - c. Osmolite HN.
 - d. Criticare HN.
7. All of the following points are important to pass along to persons purchasing enteral nutrition products EXCEPT:
 - a. they are sterile until opened.
 - b. they are excellent media for microbials.
 - c. they should be kept at room temperature and discarded 96 hours after opening.
8. Which of the following is a product that could be suggested on request for an enteral supplement that has low residue and is isotonic?
 - a. Glucerna
 - b. Glucola
 - c. Isocal
 - d. Isolyte
9. All of the following tissues require glucose exclusively for their energy source EXCEPT:
 - a. blood cells.
 - b. kidney.
 - c. brain.
 - d. liver.
10. Which of the following is commercially available in liquid, powder, and pudding dosage forms?
 - a. Compleat
 - b. Exceed
 - c. Precision
 - d. Sustacal

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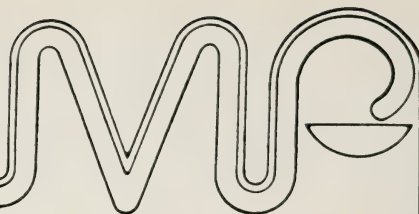
May, 1991

No. 5



University of Maryland
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SESQUICENTENNIAL



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The Maryland Pharmacist (ISSN 0025-4347) is published monthly by the Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201. Annual Subscription — United States and foreign, \$10 a year; single copies, \$1.50. Members of the Maryland Pharmacists Association receive The Maryland Pharmacist each month as part of their annual membership dues. Entered as second class matter at Baltimore, Maryland and additional mailing offices. Postmaster: send address changes to: The Maryland Pharmacist, 650 West Lombard Street, Baltimore, Maryland 21201.



Maryland's School of Pharmacy for 150 Years!

A Guest Commentary

People have a penchant for counting birthdays and anniversaries, as if just hanging in there for another year deserves a celebration. But some birthdays *are* special, and the School can count more birthdays now than all but three others of the nation's 74. In 1991 our school of pharmacy became 150—the double-diamond anniversary—our sesquicentennial!

The School of Pharmacy has made an impact on the state of Maryland for reasons other than just being old. Throughout the years it has been an institution whose faculty, staff, students, and alumni have not been afraid to do the right thing—or to do things right.

Looking to the future, ground is being broken for a new building at Penn and Lombard, diagonally across from the Kelly Building, that will provide new space for the Pharmacokinetics Biopharmaceutics Laboratory and for the Department of Clinical Pharmacy. Although these groups will be separate from Pharmacy Hall, the arrangements will be more efficient and planned the way we want it.

The new celebration of our sesquicentennial will continue throughout 1991, although it will be tough to top the dinner dance at the B&O Railroad Museum that kicked off our year. The sesquicentennial exhibit featuring the pharmacist as an educator was featured at the Science Center during March and April, and we are grateful to MPhA for loaning us the magnificent pharmacy display case for the exhibit. One of the MPhA show globes is featured in our sesquicentennial poster that most pharmacists in Maryland should have received by now.

Later in the year the celebration will continue with commencement activities featuring the award of an honorary Doctor of Laws to Joseph Williams, a Remington Medalist who is Chairman of Warner Lambert. A corps of pharmacy students and practitioners is planning an outreach program involving drug education programs in shopping centers throughout Maryland. An alumni weekend is coming up in the fall, as well as a science symposium.

Our alumni and friends already have contributed generously of their time and resources to help make our sesquicentennial a success. The celebration is just beginning. I hope that you will join us!

David A. Knapp, Ph.D.

Acting Dean

Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Correspondence Course

Counseling Consumers on Self-Therapy of Nocturnal Leg Cramps

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

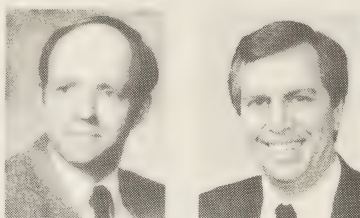
Goals

The goals of this lesson are to:

1. describe suspected etiologic causes and aggravating influences for nocturnal leg cramps;
2. discuss therapy for their self-

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treatment; and

3. present important information to convey to individuals who wish to self-treat nocturnal leg cramps.

Objectives

At the conclusion of this lesson, participants should be able to:

1. demonstrate knowledge of the suspected causes and aggravating factors of nocturnal leg cramps, and describe physiologic events in their genesis;
2. identify ingredients of OTC products indicated for treating nocturnal leg cramps;
3. choose the pharmacologic and toxicologic considerations, warnings and precautions, and important drug interactions of quinine; and
4. choose from a list, important advice to communicate to individuals to assure that self-therapy of nocturnal leg cramps will be maximized.

Nocturnal leg cramps occur in millions of Americans, are not life-threatening, and their cause is unknown. They are often referred to as trivial...except by those who experience them! Nocturnal leg cramps are the fourth leading cause of insomnia in America. They are distressing and painful.

Background

Nocturnal leg cramps are sudden, involuntary, spasmodic and unbearably

painful muscle contractions that can last up to 10 minutes. They are recumbency-induced and usually begin within a few hours of onset of sleep. They may be localized to a certain muscle group, or spread to adjoining ones. The calf muscle (gastrocnemius) is most frequently involved. The pain is often called a "charley horse."

Leg cramps most commonly occur in persons of middle age and beyond. They are more prevalent in women. They may occur in persons suffering from venostasis (poor venous blood flow) in the legs, persons with foot deformities and spinal cord disorders, and during pregnancy.

The cramps are referred to as *stremma*, from the Greek term meaning "anything twisted up together." During a leg cramp, the muscles contract violently. The affected area feels extremely hard to the touch, and pain is often described as sharp, shooting, and excruciating. The leg muscles may be tender for 24 hours or more afterwards.

Leg cramps often fail to follow a predictable pattern of severity, duration, or occurrence. They may appear after a daytime session of heavy physical activity or exercise. But they may also appear after a sedentary period. Sufferers report that they may occur regularly for a few nights or weeks, then spontaneously disappear. Other times, they happen nightly, for years. They may occur only once, or repeatedly during the night. They can become hazardous to health when, because of their severity and expectation for occurring, the sufferer is afraid to go to bed at night.

The etiology of profuse bursts of electrical activity in the leg muscles that precede cramping is unknown. Postulated causes include (1) muscle anoxia due to arterial insufficiency or enhanced oxygen requirement; (2) excessive venostasis secondary to sudden emptying of small venules into

larger ones; and (3) accumulation of products of muscle metabolism, such as lactic acid. In the latter case, these metabolites may pool due to venostasis.

Cramps can also be caused by stretching or restless leg movement. The majority of victims do not have neuropathic disease. Nocturnal leg cramps occur relatively frequently in athletes and others who exercise vigorously. They are also common in persons with circulatory impairment, but are independent of arterial circulation.

Precipitating factors include water and electrolyte loss. Hyponatremia, hypokalemia, and hypocalcemia all correlate with leg cramps. These conditions can be especially significant in patients on diuretics because of the potential for sodium and potassium depletion. Iron deficiency anemia, prolonged exposure to cold, malignancy, peripheral neuropathy, chronic pulmonary disease, diabetes mellitus, and prostatitis are variously cited as precipitating causes. Drugs reported to cause cramping include clofibrate and beta-adrenergic stimulants.

Remedies

Numerous home remedies have been advocated for relieving nocturnal leg muscle cramping. These include wrapping the legs with cloth; applying heating pads, hot water bottles, or cold packs; immersing the affected limb in warm to near-scalding water; and actively massaging the area. Elevating the foot of the bed, using blanket supports to keep bed clothes off the legs, and drinking tonic water (more on this later) are also advocated.

One novel recommendation is to place a three-inch horseshoe-shaped magnet under the affected limb, between the mattress and lower bed sheet. This supposedly alters the course of electrical current that initiates cramping. So when a cramp begins, the leg is moved over the magnet which prevents the problem.

To avoid daytime cramping and supposedly modify nocturnal cramping, persons who are on their feet for long periods (e.g., pharmacists, cashiers) should stand on a flexible mat. They should also periodically flex their leg muscles by moving about. The procedure that is most frequently recom-

mended is to stand and flex the foot by raising the body onto the balls of the feet, or move the leg. Walking is often effective. These activities stretch the calf muscles and help relieve cramping.

Affected individuals also try various pharmacologic interventions, including analgesics, antihistamines, ascorbic acid, calcium supplements, and quinine. Of these, quinine is most commonly recommended. OTC products that contain quinine, used for preventing and treating nocturnal leg muscle cramps, are listed in Table 1.

Quinine

Quinine has a long and colorful history. It was the mainstay for treatment of malaria during World War II, but its use for this has decreased since then. Quinine remains the OTC drug-of-choice for self-treatment of nocturnal leg muscle cramps. It is also commonly prescribed for this purpose by physicians. As stated earlier, some individuals drink tonic water because of its quinine content to relieve nocturnal leg cramps.

Quinine's use in treating nocturnal leg cramps began in 1936 with a literature citation that the drug successfully relieved leg muscle cramps in myotonia congenita, a rare congenital disorder of generalized muscle rigidity and spasm. This observation was soon extended to more generalized use to relieve muscle spasm, and to treat nocturnal leg cramps.

A number of observers has also reported that nightly doses of quinine sulfate 300 mg are significantly supe-

rior to placebo in lessening the number, severity, and duration of nocturnal leg muscle cramps.

The National Disease and Therapeutics Index (NDTI) surveys drug usage based on information supplied by office-based physicians. To illustrate the extent of quinine usage, it estimates that the drug was mentioned approximately 175,000 times in 1983. Of these citations, 64 percent were for use in relieving leg muscle cramps.

There have been no large-scale studies undertaken to investigate the precise cause(s) of nocturnal leg muscle cramps. Indeed, clinical evidence to support the effectiveness of quinine in alleviating leg cramps is limited. But quinine's place in therapy is nevertheless well recognized and firmly established. *The Medical Letter* editors recently suggested that quinine sulfate (64.8 to 260 mg) at bedtime could relieve nocturnal leg cramps, despite the paucity of scientifically-based evidence.

Pharmacokinetic Considerations. Quinine is rapidly, and almost completely, absorbed from the proximal portion of the small intestine, even in persons with diarrhea. Peak plasma levels following a single oral dose occur within 1 to 3 hours. Seventy percent is bound to plasma protein. Quinine is lipid soluble, metabolized to 90 percent in the liver, and excreted primarily in urine. The drug does not accumulate in the body; a dose will be almost completely cleared within 24 hours. Renal excretion is doubled when urine is acidic rather than alkaline. It is normally taken as the sulfate salt.

TABLE 1

Representative OTC Products that Contain Quinine Sulfate

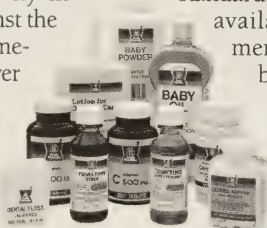
Product (Manufacturer)	Form	Quantity
Legatrin (Scholl)	Capsule	130 mg
Quine (Rowell)	Capsule	200 mg
Quinine Sulfate (Lilly)	Capsule	130 mg
Quinine Sulfate (various)	Capsule	195 mg 200 mg 300 mg 325 mg
	Tablet	325 mg
Q-vel Softgels* (Ciba Consumer)	Capsule	65 mg

*Also contains 400 units vitamin E.

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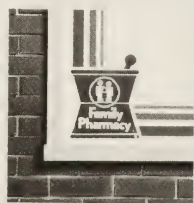
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Mechanism of Action on Skeletal Muscle. Quinine exerts a direct action on skeletal muscle to lengthen its refractory period, and decrease its response to mechanical and electrical stimulation. Response to a single stimulus is reduced, and motor end plate excitability is lessened. Quinine can antagonize the action of acetylcholine on skeletal muscle as effectively as curare. Recall that acetylcholine is the neurotransmitter that stimulates motor end plates in skeletal muscle to contract.

Adverse Effects. Taken in therapeutic doses for a short period of time (10 days or less), adverse effects to quinine are rare. Since quinine is a marked local irritant, gastric pain, nausea, vomiting, and diarrhea following larger doses have been mentioned in the literature.

A dose of approximately 4 gm is reported to be toxic, and 8 gm lethal, to an adult. Therapeutic doses taken over prolonged periods, or acute overdose, may cause appearance of symptoms of **cinchonism**. This syndrome includes the classical cluster of nausea and vomiting; dermal manifestations of rash, flushing, pruritus, and angioedema; headache, tinnitus, and hearing and visual disturbance. Visual disturbance includes double vision (diplopia), mydriasis, photophobia, scotomata (empty spots in the field of vision), distorted color perception, night blindness and constricted visual fields. Permanent blindness is rare, but has resulted.

Central nervous system symptoms of toxicity include respiratory stimulation followed by depression, confusion, feeble pulse, and delirium. Fainting spells, cardiac arrhythmias, and myocardial depression are also signs of toxicity. Quinine is an abortifacient. Neutropenia and thrombocytopenia occur on rare occasion following nightly doses of 300 mg for treatment of leg cramps. Renal damage, asthma in hypertensive persons, and photosensitivity reactions have also been rarely reported.

Quinine exerts a direct hypoprotrombinemic action. It may therefore add to the anticoagulant action of warfarin (Coumadin, etc.). This suspected drug-drug interaction is not fully understood, but caution during concomitant administration is advisable.

Quinine also reduces digoxin elimination. In one study, digoxin levels were increased by 75 percent following four days of quinine therapy. Therefore, patients stabilized on digoxin should be monitored for toxicity or therapeutic failure when quinine is added to or discontinued from their therapy.

While still uncommon, the incidence of quinine poisoning is reported to be increasing. Most poisonings are reported in children who accidentally ingest medication prescribed for other family members. Other cases result from attempted abortion or suicide. Poisoning is of special concern because of quinine's long-term effects on vision, and occasional reports of death at fairly low doses.

Dosing. Nocturnal leg cramps are normally relieved by OTC products with doses of quinine sulfate of up to 260 mg daily doses, or larger doses by prescription. Some individuals experience prolonged relief following limited therapy of several days to a week.

Quinine has been reviewed by the FDA Advisory Review Panel on OTC Analgesics and Antirheumatic Drug Products. Panel members reported that the drug has analgesic, antipyretic and muscle relaxant actions, but also has an unfavorable benefit-to-risk ratio due to its potential for toxicity. They therefore recommended against self-treatment of nocturnal leg cramps. This evaluation was based on use of doses in the range of 300 to 600 mg, with daily administration up to 2 gm.

Another FDA panel, the Advisory Review Panel on OTC Miscellaneous Internal Drug Products, also reviewed available data. The panel acknowledged that quinine causes adverse effects, but reported that the drug appears to be relatively safe when taken over prolonged periods of time.

This panel based its observations on doses of 200 to 325 mg daily, which are closer to those generally recommended for relief of nocturnal leg muscle cramps. The panel stated further that, in spite of the fact that the drug is both widely prescribed by physicians and used by self-administration for treating nocturnal leg cramps, it has never been scientifically tested to establish its precise therapeutic role. It therefore recommended that quinine be further evaluated for this use to establish safety and effectiveness. Manufacturers were in-

vited to conduct clinical testing to establish these criteria. Quinine may remain on the OTC market for self-treatment of nocturnal leg cramps with a recommended dosage of 260 mg daily in divided doses, until the studies are completed and FDA makes its final ruling.

Other Drugs

Vitamin E. Several citations in the medical literature recommend the use of vitamin E in treatment of nocturnal leg muscle cramps. In one report, 103 of 125 patients reportedly experienced complete relief, and another 13 had 75 to 90 percent relief of cramping with doses of 300 or 400 units daily. Investigators indicated that their interest in the vitamin was based on earlier serendipitous observation that patients taking it for dermatologic conditions experienced relief of leg cramps. They argued that vitamin E is preferred over quinine because it is safer.

It is generally agreed that vitamin E plays an integral metabolic role in practically all body tissues. It protects vital cell membranes and intracellular structures by preventing lipid peroxidation (antioxidant activity). It also facilitates oxygen use in normal metabolic processes.

There are huge gaps in available knowledge concerning the vitamin's safety. Vitamin E is often purported in the popular press to be safe. These citations indicate that the vitamin is tolerated in seemingly limitless doses and is without undue toxicity.

But the medical literature clearly illustrates that this is not so. Vitamin E causes definite pharmacologic and toxicologic actions. Clinical disorders attributed to its overuse include dizziness, headache, fatigue, nausea and vomiting with abdominal cramps, muscle weakness, mouth sores and chapping of the lips. Thrombophlebitis, hypertension, gynecomastia and breast tumors have also been reported.

The safe and effective dose of vitamin E for prevention and/or treatment of nocturnal leg cramps is not known. FDA will not permit such a claim until its safety and effectiveness are proven.

Counseling Consumers on Therapy of Nocturnal Leg Cramps

Many reports describe the use of quinine in alleviating nocturnal leg

muscle cramps. Most neither strongly support nor condemn this use. Data have been largely generated from uncontrolled studies or anecdotal observations. But the fact is that quinine continues to be prescribed for this affliction.

If it is going to "work," quinine will probably act within a day or two of onset of therapy. Short-term quinine therapy is sometimes associated with continued alleviation of cramps after discontinuing the medication. Individuals should therefore stop taking it periodically, following several continuous pain-free nights, to determine whether therapy is still needed.

For quinine to exert maximal activity with as few adverse effects as possible, certain precautions should be taken. Therapy should be interrupted if an individual develops a feeling of ringing, buzzing, thumping, or other strange sensations in the ears, or any change in hearing. Quinine likewise should be stopped if it causes skin rash, bleeding, or discoloration; changes in vision or dizziness; severe gastrointestinal discomfort; headache; or shortness of breath or troubled breathing. These are signs of cinchonism, which warn of impending toxicity.

Quinine should be taken after meals, or along with a snack to reduce occurrence of gastrointestinal discomfort. Doses should be kept at the lowest level which afford relief of cramps, but which cause minimal gastrointestinal symptoms.

Quinine should not be administered to children under age 12 years without instruction from a physician. Quinine-containing products should be kept out of the reach of children.

Affected individuals should experiment by laying in different positions, and avoid those that are more apt to cause cramping.

Occasionally, cramping may be sufficiently severe to prevent sleeping, walking, or other activities. When this occurs, the individual should consult a physician for a complete medical examination. Such cramping could result from serious pathology, such as hypocalcemia, cirrhosis, or circulatory damage.

Appropriate advice for consumers who purchase OTC products containing quinine for self-treatment of nocturnal leg cramps is to follow the directions explicitly. The recommended dosage for the 130 mg capsules is 2

capsules when leg cramps occur. To prevent nocturnal leg cramps, the dose is 2 capsules taken two hours before bedtime. No more than 2 capsules should be taken in any 24-hour period.

For the 65 mg capsules, the recommended directions are 2 capsules after the evening meal and 2 more at bedtime, with no more than 4 capsules taken in a 24-hour period. In either instance, the patient should not self-medicate for longer than 10 days.

These products should *not* be taken without medical supervision if the person is pregnant or breast feeding, under the age of 12 years, or allergic to quinine or quinidine.

Quinine-containing products can be taken with or after meals to minimize GI tract upset. When leg cramps do not occur for several consecutive nights of therapy, the person should stop taking the product to determine whether it is still necessary.

Cramping that cannot be alleviated with quinine, or other home remedies, may respond empirically to other therapy. This includes opioids, propranolol, chlorpromazine, chloroquine, clonidine, levodopa, aminophylline, pentoxifylline, carbamazepine, verapamil, oral iron, and various benzodiazepine derivatives.

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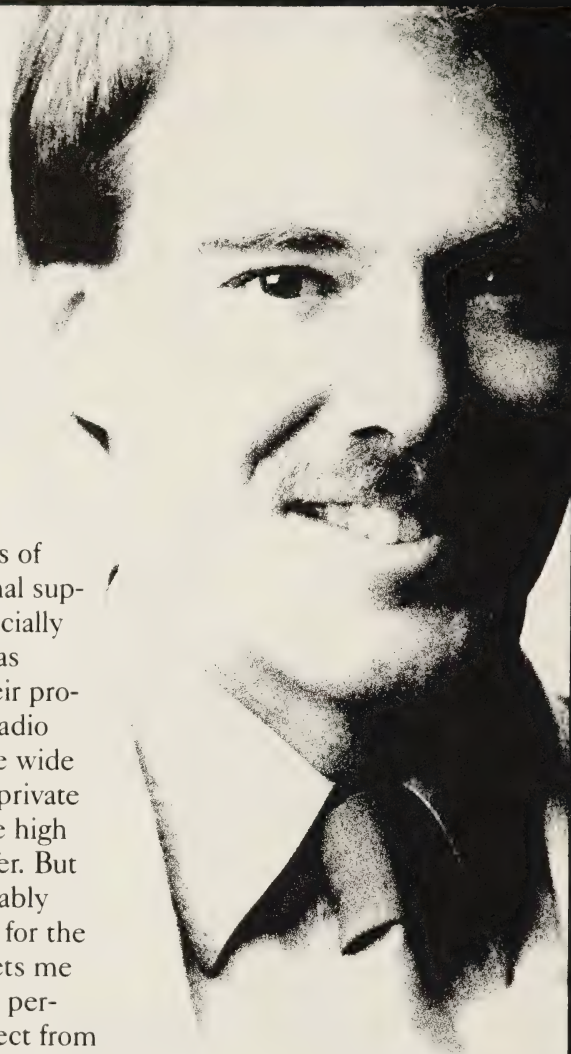
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Drug Abuse Prevention: A Complex Undertaking

Tony Tommasello
Office of Substance Abuse Studies
University of Maryland School of
Pharmacy

America continues to react to a drug abuse epidemic that can be traced back to at least the 1960's. The prolific synthetic production of pharmaceuticals collided with an emerging desire to use drugs as a means of self-exploration on the part of young adults. The resultant wave of self-medication created a crisis in American health care. The initial reaction took the form of overworked hospital emergency rooms treating victims of drug overdose, the emergence of neighborhood crisis counseling centers, and the establishment of specialized drug treatment clinics.

Having navigated the troubled waters of the subsequent 30 years, America arrives at the 1990's with a more mature system of care for the drug abuser and chemically dependent patient. Research and clinical experience have yielded a better understanding of the addicted patient and how to treat him. The need to understand clinical management concepts related to addiction treatment is now part of the mainstream of medical practice. Unfortunately there still remain significant barriers that block access to care for many who want help.

Prevention is another issue entirely. We continue to flounder in our efforts to initiate effective primary prevention strategies. We seem to be attracted to those efforts which focus on high risk youth. We can call it a problem of the young rather than recognize it as a failure of our society. Thus we create "say no" programs, peer resistance strategies, life skills training, and social inoculation (1). We shy away from prevention approaches that attempt to deal with social structure, perhaps because it seems too mind boggling a task. In our focus on

TABLE 1
Percent of Adolescents Using Substances by Frequency of Use
Maryland Adolescent Survey 1988-1989
Statewide Estimates

Substances	6th Grade			8th Grade			10th Grade			12th Grade		
	Ever Used	Current Use	Frequent Use	Ever Used	Current Use	Frequent Use	Ever Used	Current Use	Frequent Use	Ever Used	Current Use	Frequent Use
<i>Alcohol</i>	50.5	9.5	1.2	64.3	27.2	4.1	81.5	50.5	9.4	87.3	60.2	13.5
<i>Tobacco</i>												
Cigarettes	30.9	3.6	1.4	45.5	11.3	6.3	59.5	19.0	14.6	64.5	24.1	19.5
Smokeless tobacco	6.2	0.6	0.1	11.7	1.9	0.8	17.5	3.7	1.8	19.5	3.9	2.3
<i>Drugs</i>												
Amphetamines	1.8	0.4	0.1	5.8	1.8	0.5	13.7	4.7	1.2	15.6	3.7	1.4
Amyl/butyl nitrates	1.1	0.5	0.3	2.6	1.2	0.2	8.0	1.7	0.4	10.9	2.3	0.7
Barbiturates	0.9	0.2	0.1	2.8	1.3	0.3	5.5	1.6	0.2	5.8	1.6	0.5
Cocaine												
(excluding crack)	1.8	0.6	0.3	3.5	1.6	0.6	7.5	2.4	0.4	10.6	3.1	0.7
Crack (cocaine)	1.4	0.4	0.2	3.2	1.3	0.6	5.6	1.9	0.4	6.1	1.7	0.6
Designer drugs	0.6	0.3	0.3	1.6	0.7	0.3	2.9	0.8	0.3	2.6	0.9	0.6
Hallucinogens	0.5	0.1	0.0	2.7	0.7	0.2	8.3	3.2	0.5	10.2	3.9	0.9
Heroin	0.8	0.3	0.1	1.7	0.6	0.2	2.1	0.5	0.2	1.9	0.9	0.3
Marijuana/Hashish	3.2	0.6	0.2	13.1	3.5	0.9	31.5	12.5	4.1	43.2	1.5	5.7
Methamphetamines	1.0	0.5	0.1	3.7	1.1	0.3	9.9	2.9	0.6	11.7	2.2	0.9
PCP	0.9	0.2	0.2	3.0	3.9	0.2	9.3	2.7	0.9	12.9	2.7	0.8
Prescription												
pain killers	9.3	2.3	1.0	13.3	4.7	1.3	21.0	6.9	2.0	25.8	6.3	1.9
Steroids	2.0	0.7	0.5	2.3	1.2	0.5	2.2	0.9	0.5	3.1	1.7	0.7
Tranquilizers	1.5	0.4	0.2	2.9	0.8	0.3	4.3	1.3	0.3	5.8	1.7	0.4
<i>Solvents</i>	12.9	2.2	0.7	18.5	4.4	1.2	16.3	3.2	0.6	14.6	2.7	0.8

youth we may develop programs that fail to take into account their resourcefulness. Instead society continues to treat them like property, minimizing their personal capabilities and attempting to coerce and direct their decisions.

If kids were as ineffective decision makers as they are portrayed to be, they would all be sociopathic, HIV positive, drug addicts due to their inability to resist modeling the violence displayed on television, by engaging in prolific unprotected sexual practices, and by using drugs without concern for acute effects and addition. The "just say no" campaign, while laudable in its goals in effect tells adolescents: "You have no identity of your own. We know what is best for you. You will do as we say" (2). In short children are treated like property to be molded to our liking. The popularity of "just say no" demonstrates the lack of tolerance on the part of

adults for any drug experimentation by adolescents. However, as one street youth put it: "It's hard to 'say no' when you have nothing."

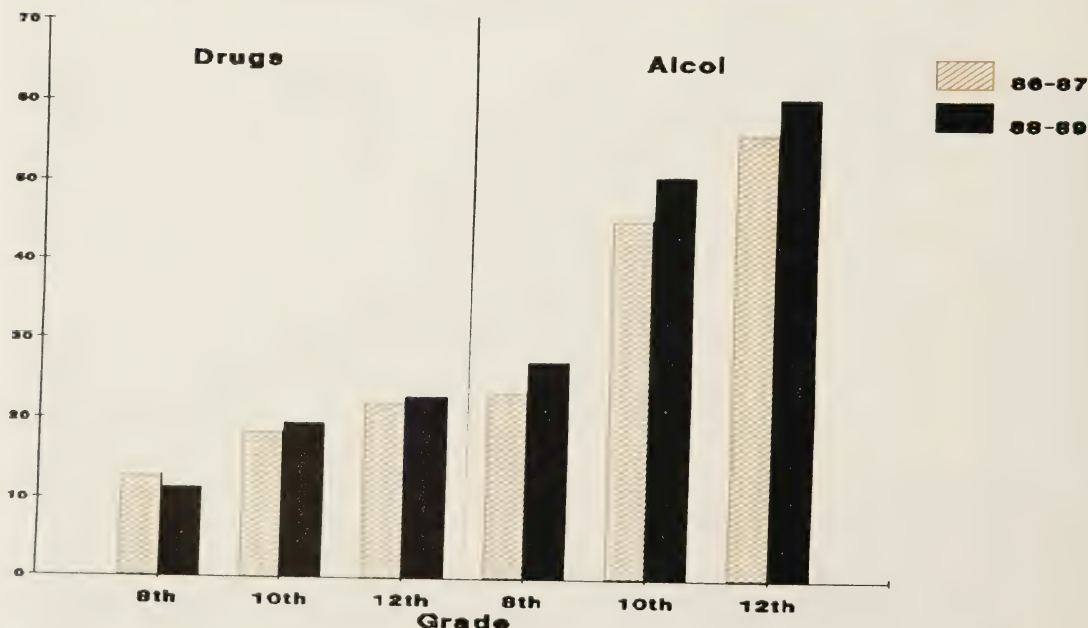
Prevention in a broad sense involves supply and demand. The use of resources in the prevention effort depends on the degree to which one believes that one approach will work better than another. Supply reduction strategies are short sighted, but highly visible. The picture of the bust, of dealers being carted off to prison, of massive quantities of drugs seized make good media entertainment. Unfortunately we know how quickly and viciously drug territory, available after the arrest of a high level dealer, is reclaimed. We also know that large drug seizures often have no impact on price or availability of substances in high demand. Effective long range efforts in prevention must be geared toward demand reduction.

Research has found that drug ex-

perimentation during adolescence in itself is not synonymous with deviance or pathology (3). High school surveys nationwide and in this state indicate that most youth try alcohol and cigarettes before graduating high school and a large portion have tried marijuana, amphetamines, cocaine, solvents and PCP (see table I and figure I). It appears that the notion of wiping out adolescent inquisitiveness about the world around them is unlikely to succeed. Indeed would we want to do so?

Isn't the very notion of prevention involved with the process of helping adolescents make positive choices, of building supportive environments around them, in short fostering protective mechanisms for the future? In the words of one researcher: "This approach stems from the related notion of resilience, the term used to describe the positive pole of individual differences in people's response to stress and ad-

FIGURE I.
PERCENTAGE OF MARYLAND ADOLESCENTS
REPORTING CURRENT USE OF DRUGS AND ALCOHOL
1986-87, 1988-89 ADOLESCENT SURVEY



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versity." Protection involves, not the evasion of risk, but the successful engagement with it and resultant adaptive changes that follow successful coping (4). As prevention expert George Albee put it ten years ago, we must build a competency model to replace the defect model.

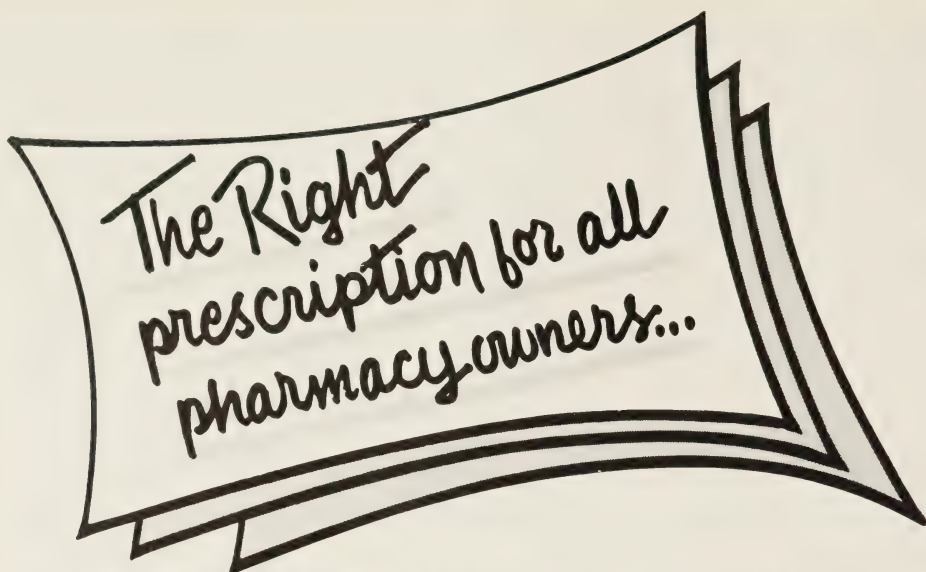
Addictions researcher George Valliant emphasizes the importance of social stability as a protective factor against alcohol abuse (5). Broken homes, unstable home environments, and absent parents increase the likelihood of adult alcoholism. In a recent study by the department of psychology at UM College Park we found that psychosocial competency was associated with the perception by youth of a home environment high in supports and low in threats. Psychosocial competency in turn was negatively related to the degree of drug involvement. The more competent the individual the less the degree of drug involvement (6).

As respected leaders and specialists in drug information, pharmacists should be on the front line in these efforts to prevent drug abuse. While we can't abandon the law we can redirect our manpower and financial resources into long range prevention strategies. It is reasonable to believe that prevention can come through education, the promotion of high ideals, and a substantial investment in creating supportive rather than threatening home environments. In the search for "high risk youth" we can identify those who come from low support, high risk areas and help them construct better lives by providing them with supports and better life options.

It appears that in a sense America is addicted to the quick fix. We all want to do something to deal with what is an apparent urgent problem and we want to see immediate results. Long range prevention strategies don't offer the glamor of headline news. It takes a long dedi-

cated effort. The very young should be educated about the proper use of medicine. Those a little older should learn about the effects of psychoactive drugs and to recognize early signs of drug dependency in themselves and others. Everyone needs to realize that drugs provide no magical solution to life's problems. Accurate scientific information about drug effects should be easily available to those who want it. Treatment resources should be easily identifiable and accessible. Activities that represent alternatives to drug use should be funded and vigorously promoted. These activities must be accessible to youth in every sense of the word (ie. physically, philosophically, temporally).

In *Huckleberry Finn*, Mark Twain tells a story of how society defines children as property. Children "belong" to their parents, their perspectives are devalued, and they are considered incapable of responsible judgement or conduct. As seen



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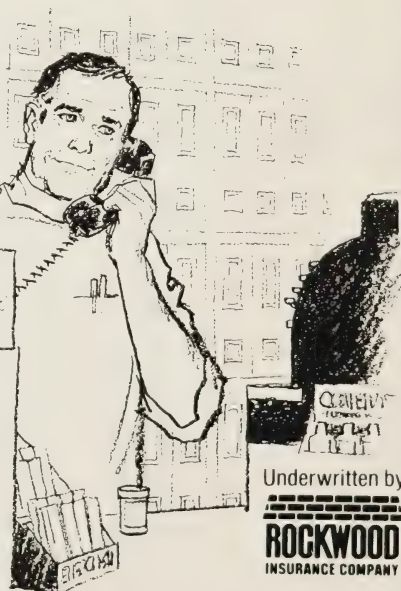
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from the adults' perspective the actions of youth are foolish and unplanned. From the youngster's point of view a different perspective emerges: In the story Huck runs away and joins Jim, an escaped slave. Huck first decides to turn Jim in, but recants, concluding:

"They (men looking for escaped slaves) went off and I got aboard the raft (where Jim was hidden), feeling bad and low, because I knowed very well I had done wrong, and I see it warn't no use for me to try to learn to do right; abody that don't get *started* aright when he's little ain't got no show —when the pinch comes there ain't nothing to back him up and keep him to his work, so he gets beat. Then I thought a minute,

and says to meyself, hold on; s'pose you'd 'a' done right and give Jim up, would you feel better than what you do now? No, says I, I'd feel bad—I'd feel just the same way I do now. Well, then, says I, what's the use you learning to do right when it's troublesome to do right and ain't no trouble to do wrong, and the wages is just the same? I was stuck. I couldn't answer that. So I reckoned I wouldn't bother no more about it, but after this always do whichever come handiest at the time."

If we dare learn the perspective of youth and begin to collaborate with them, we may change the way we develop and conduct drug abuse prevention programs.

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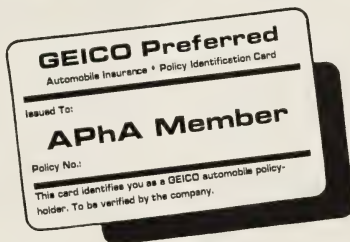
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UMAB Campus President Erol Reese chats with UMAB alumni pharmacist and Delegate Donald B. Elliott.



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Mrs. Arlene Padussis, Dr. Ralph Shangraw—recipient of the 1991 AACP Educator of the Year Award—and former Board of Pharmacy member Anthony Padussis.



Students Lisa Esser, Tina Koehle and David Chen talk with Delegate Elliott and MPhA Executive Director David Miller (left to right).



Delegate Don Fry, Dr. Donald O. Fedder, and Delegate Kenneth Schisler at the State House reception.

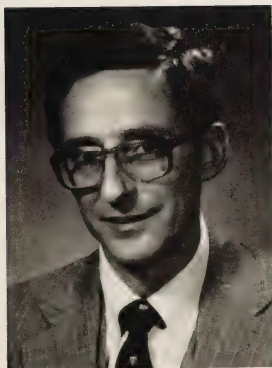
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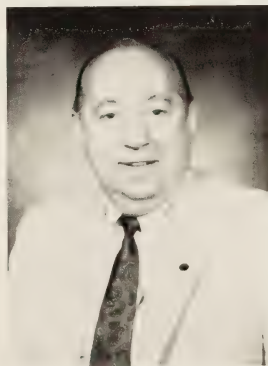
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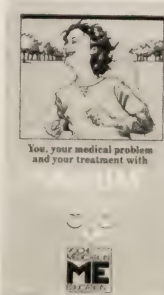
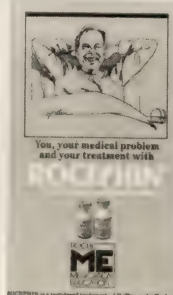
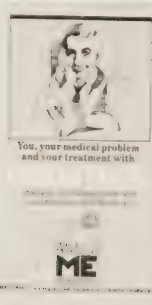
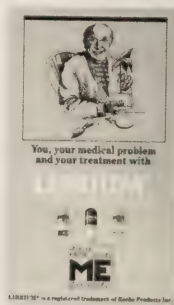
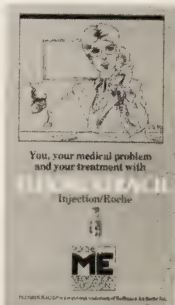
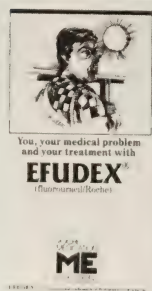
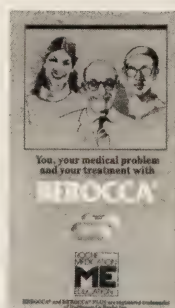
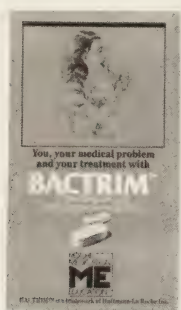
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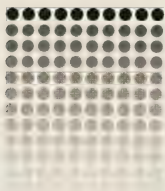
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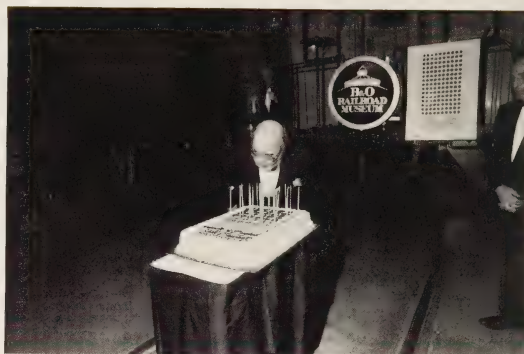


University of Maryland School of Pharmacy Sesquicentennial Dinner Dance January 20, 1991

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Among the guests, Dr. and Mrs. Ralph Shangraw, Mrs. Ann Leavitt, Daisy Gue, and Margaret Beatty (left to right).



D. J. Morrison, 1991 Alumni President Kathy Gauthier, MPhA Executive Director David Miller and his wife Penney (left to right).



Pharmacy students and their guests—David Moon, Suk Yi, Mark Neal, Alisa Billington, Bang Hee Kim, Roger Guidi, Kuang Trunka, and Steve Beres (left to right).



Following the dinner, everyone joined in to "slide."



Dr. and Mrs. Frank Palumbo, Dr. Dee Knapp, and Dr. Marilyn Speedie (left to right).



Elaine Jackson, Caroline Footman, Ricardo Robinson, and Williestine Dargan (left to right).



Audrey Salabes, MPhA Trustee Arnold Davidov, Drs. David and Dee Knapp (left to right).



Margaret Beatty, Dr. Marilyn Speedie, Dr. Stuart Speedie, and Mrs. Ann Leavitt (left to right).



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Daniel K. Hays is a financial consultant with Advest, Inc. in Lutherville, Maryland. If you have any questions, he can be reached at 800/272-7368.

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The Founding of the Maryland College of Pharmacy

Benjamin F. Allen, dec.

The first suggestion of a college of pharmacy in Baltimore emanated from Dr. William R. Fisher (he held the degree of M.D.), a native of Philadelphia who settled here in 1827 at the age of 19, and established a pharmacy in the city about 1834. He was professor of botany in the School of Arts and Sciences of this university and one of the leading spirits in the Maryland Academy of Science and Literature. In 1837, he was made professor of chemistry in the School of Medicine.

Of Dr. Fisher's "plan" nothing is known except that he had formed one, and that it met with favor among his colleagues of the Medical and Chirurgical Faculty. A sudden illness prevented his participation in its execution. He returned to Philadelphia in 1839 and recovered sufficiently to occupy a professorship in the Philadelphia College of Pharmacy. He died at Hohnesburg, near Philadelphia, in 1842 at the early age of 34.

Also, in 1837, a convention of Eastern Shore physicians in Easton, Md. made a demand on the General Assembly in Annapolis for the establishment of a college of pharmacy.

The School of Pharmacy of the University of Maryland, originally the Maryland College of Pharmacy, is now in the one hundred and thirty-fifth year of its existence (The oldest pharmacy school of the south). In 1841, there were 77 drug stores in Baltimore City. The more forward-looking proprietors of these stores, realizing that a broader and more thorough education and training than could be obtained

through employment in a drug store must be provided for their apprentices if the citizens of the Commonwealth were to be properly served, joined with some of the more progressive physicians of Baltimore City (several were associated with the University of Maryland) in organizing the Maryland College of Pharmacy, which was incorporated on Jan. 27, 1841, and which began to function as a teaching institution in November of the same year.

A store of this early period was that founded in 1824 by Thomas G. Mackenzie, northeast corner Baltimore and Gay streets. Associated with Mr. Mackenzie in this venture were his father and two brothers, all prominent physicians.

Thomas G. Mackenzie (1802-73) was the great moving spirit in establishing the Maryland College of Pharmacy. He was one of the organizers (1840) as well as one of the incorporators (1841) of the college. The lectures at the new institution were given in his little office (back of drug store) which was not larger than the hall of a home. In the absence of the regular lecturers, Mackenzie gave occasional talks to the students. The college functioned at this location during the period 1840-44. The first class consisted of six young men, but only three graduated in 1842 (Frederick A. Cochrane, Alpheus P. Sharp and William S. Thompson).

In the spring of 1844, a committee from the Maryland College of Pharmacy was appointed to endeavor to make an arrangement with the Faculty of Physic of the university for a union of the two institutions.

On April 24, 1844, the Maryland College of Pharmacists entered into an arrangement with the Faculty of Physic of the University of Maryland whereby the lectures of the pharmacy college were to be united with those of the university so as to enable the students of medicine to

have the benefit of the lectures on pharmacy, in return for which the students of pharmacy were to enjoy the privilege of attending the lectures on chemistry by the dean of the Faculty of Physic. The lectures on pharmacy were delivered in the amphitheater of "Old Main" (now Davidge Hall) located at Lombard and Greene Streets. (Tradition has it that a large crowd of anxious Baltimoreans viewed the spectacular firing on Fort McHenry from the front entrance of this building, the events in other words that led to the writing of the "Star Spangled Banner" in 1814.)

At this time, it was decided to elect a professor of pharmacy to deliver the course of lectures. Dr. David Stewart, who had in this year (1844) taken his degree in medicine at the university, was elected to the professorship. The name of the chair of pharmacy thus created on April 30, 1844 was the first in this country.

David Stewart (1813-99) was born in Port Penn, Del. He arrived in Baltimore at the age of 18 to study pharmacy and chemistry. David Stewart and his brother, James opened a drug store on Charles and Lexington Streets (1839) and later at Hanover and Camden Streets (1841). He became active in politics, as well as civic affairs, and was a member of the city council (1835-37), school commissioner (1836), state senate (1840), inspector of drugs (1850-53), state agricultural society chemist (1855-62), and at the same time, professor of chemistry and natural philosophy at St. John's College in Annapolis.

The arrangement with the Faculty of Physic continued in force until the year 1847, when the interest in the college of pharmacy began to decline. For nine years the college lay paralyzed, and it was not until the year 1856 that interest in the institution again revived. On Feb. 20, 1856, 31 apothecaries met at a hall on the corner of Lexington

and Eutaw Streets and helped reorganize the college (it appears some classes may have been held at this location).

In the fall of 1856, the college rented a room at the corner of Calvert and Water Streets, fitted it with requisite furniture and apparatus, and made all arrangements for a resumption of an active college career, to which there has been no interruption up to the present time.

In 1858, the college was located in a rented room of the Maryland Medical and Chirurgical Building, 47 North Calvert Street; and in 1868, at Number 12 West Baltimore Street, a few doors west of the bridge crossing Jones Falls (Fallsway today).

Meanwhile, a large increase had taken place in the number of students, and there had also been improvements and an increase in the course of instruction, all of which necessitated the providing of larger accommodations. In accordance with these needs, in 1876 the college purchased from the city a granite-front building on Aisquith Street just north of Fayette Street, on the east side, used as a public grammar school (this building closely resembled the McKim schoolhouse which stands today at the corner of Baltimore and Aisquith Streets and is considered a gem of classic architecture).

In the spring of 1886, further increase of accommodations was called for, and it was decided to erect a new building upon the site of the one then occupied. An architect was consulted, and a handsome structure (frontage of 67 feet and a depth of 85 feet, and 3 stories high) was erected at a cost of \$35,000 and occupied during the latter part of the session of 1886-87.

About 1898, the subject of a union of the college with the University of Maryland became first bruited about as a possibility. The formal mention of union was made by the dean of the Faculty of Physic, at the annual meeting of the Medical Alumni Association in this year. He spoke of proposed new schools or faculties, especially of the purpose

of the authorities of the university to seek affiliation with St. John's College (Annapolis) and the Marland College of Pharmacy. Also of considerable interest is that back in 1882, the Faculty of Physic of the University of Maryland secured a charter from the legislature of the State of Maryland for a department of pharmacy to be added to the School of Medicine.

The legislature approved a supplementary act on March 21, 1882 authorizing the regents of the university to grant the degree of Doctor or Licentiate in Pharmacy upon any one who had served an apprenticeship of four years with some competent pharmacist, and who had attended at least two full courses of lectures in the theory and practice of pharmacy, and at least one full course in qualitative analysis, and at the time of receiving the degree was at least 20 years old.

Therefore, the Faculty of Physic made the first overtures which were favorably received by the authorities of the college, and the union was officially concluded on July 7, 1904 when the Maryland College of Pharmacy became the Department of Pharmacy of the University of Maryland.

By this arrangement, the college assumed the same relations to the university as the Department of Dentistry (established in 1882). Besides the greatly improved location and the very desirable and stimulating influences of university life, the students were able to participate in medical department lectures and laboratory instruction.

Accommodations were provided for this department in the new Dental Building, erected in 1903-04, on the east side of Green Street, corner of Cider Alley. (This building, although no longer devoted to its first use, has been thoroughly overhauled many times, and is now known as the Medical Technology Building, 31 South Greene Street.)

Classes for the session 1904-05 opened in the building on the university grounds, corner of Greene and Lombard Streets. The office and pharmacy laboratories were located

in the new Dental Building. The chemistry and microscopical laboratories were located in the Gray Laboratory (erected about 1894 and still in active operation today, situated behind the old medical building now known as Davidge Hall). Lectures were held in Gorgas Hall of the Dental Building and in the amphitheatre of the old Medical Building (erected in 1813).

The change from an isolated school to a department of a university proved satisfactory and advantageous. The university authorities felt that they had gained in this college, with its fine traditions and its long and successful career, a valuable ally and associate. The pharmacist, with his systematic habits and business methods, and, above all his common sense ideas—which are not perhaps so common or conspicuous in our less practical professions—was expected to bring to bear upon the staid circles an influence and an example that would contribute powerfully for their betterment.

In 1904, when the Maryland College of Pharmacy (49 North Aisquith Street) terminated its independent existence and amalgamated with the School of Medicine, was also the year of the Great Fire in the "Monumental City." The blaze started on Hopkins Place near Lombard Street, the site today of the Federal Building in Hopkins Plaza.

In 1907, the university was composed of only two colleges or faculties—law and medicine—the latter having attached to it subordinate departments of dentistry and pharmacy. At this time, someone stated, it was an anomaly that the School of Pharmacy should be a mere appendage to the School of Medicine. A change which would occur if the Baltimore institution became a great state university.

In 1920, the University of Maryland (Baltimore) was merged with the Maryland State College (College Park) and the combined institutions became the state university, the old name, University of Maryland, being continued. Following this merger, the Department of Phar-

macy became the School of Pharmacy of the new University of Maryland.

On April 22, 1922, the Schools of Dentistry and Pharmacy received the deed for the property known as 27 South Greene Street, consisting of the old church and parsonage buildings of the Emanuel Evangelical Church (the present site of the Bressler Research Building). A third floor, with a stairway leading to it, was built into the body of the church building, and other necessary partitions, etc. were put in place. The School of Pharmacy moved into this building with its decorated church ceiling and stained glass windows, early in November 1922. The laboratories for chemistry and pharmacy were moved to this building. Lectures were given on the first and second floors and in Gorgas Hall of the Dental Building (some laboratories in this building were also used). The upper floors of the parsonage provided office space, as well as storage and preparation rooms.

The School of Pharmacy session of 1925-26 opened with a student body of 240. This was an increase of 141 students from the session of 1921-22. Therefore, additional space was needed not only to care for the students, but also for the increase in the number of classes due to the establishment of the three-year program.

Several alumni, disappointed in their efforts to secure funds from the State of Maryland, formed the Greene Realty Company and purchased the building at 6 and 8 South Greene Street for \$32,000 (North Hospital building occupies this site at the present time).

The building was a four story factory-type structure (often referred to in later years as the Box Factory by many former students and faculty members), and after some refurbishing, was occupied by the School of Pharmacy on Oct. 2, 1926. (This building was leased to the University of Maryland, at a nominal rent by the alumni group.)

New laboratories for dispensing pharmacy, physics and zoology were equipped in this building. The

offices, reading room and library were established on the first floor. However, the old church and dental buildings were still used for the remaining courses in the pharmacy program.

The remarkable growth in matriculation continued and additional space for the school became a necessity. In order to give the overcrowded school some more space, plans were formulated to erect a building on the northwest corner of Lombard and Green Streets. (Space in this building to be available also to the Dental School.)

In 1927, the legislature appropriated \$422,000 for the sole purpose of erecting a six-story building to be used by the Schools of Pharmacy and Dentistry. In addition, \$55,000 was appropriated so that the two schools would have adequate equipment in the way of apparatus and other necessities such as furniture. (At this time it may be interesting to know that of the expenses incurred in teaching pharmacy, \$220 of that was contributed by the annual fees from the students and only \$36.36 was appropriated by the state.)

Construction of this new modern unit of the university to meet the needs of the pharmaceutical and dental professions started in 1928 and was to be the beginning of a modern educational plant for the Baltimore schools.

The fine new structure erected by the state at the corner of Lombard and Greene Streets was dedicated on Saturday, May 10 at the close of the Great 1930 Baltimore Convention of the American Pharmaceutical Association. The formal dedication of the new building marked a new epoch in pharmaceutical education. The event emphasized the great changes which have come about in the training of those entering the pharmaceutical profession.

When the school moved into the building, a new department was instituted to give instruction in physiological drug testing, pharmacology, toxicology and therapeutics. The pioneer laboratory for "drug testing" was so successful that it was used as

a model for similar installations later installed throughout many other progressive pharmacy colleges in the United States.

Since the new building also housed the School of Dentistry, it soon became known as the Dental-Pharmacy Building (now, after extensive and expensive renovations known as the Allied Health Professions Building).

In 1954, the university received an appropriation of \$575,000 for the initial phase of a new building for the School of Pharmacy. Early in 1958 (January 6), the building opened its doors for classes. The new structure consists of a basement and two floors and is located at 636 West Lombard Street.

This building was named after Dr. H. A. B. Dunning, a distinguished alumnus of the School of Pharmacy, a chemistry professor at the school for many years, and former president of the Baltimore Firm of Hynson, Wescott and Dunning (first manufacturing company to produce mercurochrome).

The curriculum of the school, developed constantly since 1841, in keeping with the trends in pharmaceutical education, has always provided competent professional pharmacists with a good liberal and general education. Upon the successful completion of the program, graduates have always been eligible to take state examinations for licensure. For the scholastically able student, various programs also trained men and women for many positions in applied and research areas of pharmacy.

From the beginning, the school has made many noteworthy contributions to the advancement of pharmacy and is one of the trail-blazers in this field. Alpheus Phineas Sharp, one of the first graduates in the class of 1842, read the first scientific paper, entitled "On the Strength of Commercial Muratic and Nitric Acids and Alcohols," before the American Pharmaceutical Association in New York City (1855). Merck, Sharp and Dohme can trace its origin to the 1845 opening of his apothecary shop in Baltimore.

In addition to the first separate professorship in the theory and practice of pharmacy (1844), some other "firsts" include an obligatory course in analytical chemistry (1872), a separate course in prescription compounding (1900), a full-time pharmacology department (1930), as well as professorships in these areas.

In 1870, the college called the first convention of representatives of pharmacy schools to formulate uniform standards for the graduation of students. The convention was held in Baltimore at the Maryland College of Pharmacy and was the forerunner of the present American Association of Colleges of Pharmacy.

From the very beginning, the school made many noteworthy contributions to the advancement of pharmacy, and today's effective local laws for drug control are an outgrowth of efforts by early faculty members of the college. Pharmacy laws initiated and fostered were the first law to regulate the practice of pharmacy in Baltimore City (1868) and the state-wide law (1902). In 1910, the legislature provided for the appointment of a food and drug commissioner and the first one was Charles Caspari, Jr. (First dean of the pharmacy college.)

The first meeting of the American Council on Pharmaceutical Education was held in Baltimore in 1932, following efforts by the dean of the school to establish this first accreditation body for schools of pharmacy. The post office and principal business office address of the council was the School of Pharmacy (32 South Greene Street). The council was incorporated Aug. 12, 1939 under the general laws of the State of Maryland. Dean Andrew G. DuMez served on the council as secretary-treasurer (1932-48) and Past-Dean E. F. Kelly was president of the organization (1932-44).

Beginning with the school session of 1928, graduate courses were outlined, and this inaugurated a graduate work era of high grade which added much to the development and prestige of the school. The

first recipients of the M.S. degree (1930) were John C. Bauer, William P. Briggs and Frank J. Slama. On June 3, 1933 the first Ph.D. degrees were awarded to John C. Bauer and Noel E. Foss.

The Maryland College of Pharmacy and the University of Maryland School of Pharmacy provided nine presidents of the American Pharmaceutical Association from 1856-1940; two general secretaries of the association, one from 1894-1911 and the second from 1925-44; and 13 deans in schools of pharmacy.

The school revised its baccalaureate program in 1969 to include a six-month professional experience program within the final fifth year. These clinical-type clerkships, which take place in selected community and institutional pharmacies throughout the state, are accepted by the Maryland Board of Pharmacy in lieu of its traditional internship requirements. Although the question of adequate control of practical experience as a part of a well-balanced pharmaceutical education had been given much study throughout the country for many years, Maryland became the first state to eliminate the nonstructured internship. In a sense, the age-old concept of an apprentice working under the personal supervision of an experienced practitioner has been revived and modernized.

Historically, pharmacy has been a clinical-related profession. In 1975, a six-year program (Pharm.D.) was instituted to complement and enhance the baccalaureate program. The primary function of the graduate of this is to perform a clinical therapeutic service to patients and health professionals. The recipients of this professional degree (Doctor of Pharmacy) will also be capable of other roles including that of an educator in pharmacy and other health professions programs.

The Maryland College of Pharmacy was a membership institution and the officers were elected. There were 13 presidents of the college from the time of organization to several years after the amalgamation as

a department of the medical school of the university. With the change in organization from that of an independent institution to a unit of a university, the office of president was abolished and a dean was appointed to assume the responsibilities of the principal administrative officer.

Maryland College of Pharmacy Presidents

Thomas G. Mackenzie, 1840-42
Benjamin Rush Roberts, 1842-44
George W. Andrews, 1844-71
J. Brown Baxley, 1871-72
J. Faris Moore (1847), 1872-73
John F. Hancock (1860), 1873-75
Joseph Roberts, 1875-88
Edwin Eareckson, 1888-90
William S. Thompson (1842), 1890-91
Louis Dohme (1857), 1891-97
Charles E. Dohme (1862), 1897-1906
Henry A. Elliott, 1906-07
Charles H. Ware (1886), 1907-08

Dean of Faculty

Charles Caspari, Jr. (1869), 1896-1904

Department of Pharmacy (after merger with the University of Maryland in 1904) Deans of Faculty

Charles Caspari, Jr., 1904-17
Daniel Base, 1917-18
Evander F. Kelly (1902), 1918-20

School of Pharmacy (after consolidation of the University of Maryland with the Maryland State College of Agriculture at College Park) Deans

Evander F. Kelly, 1920-26
Andrew G. DuMez, 1926-48
B. Olive Cole (1913), (acting dean), 1948-49
Noel E. Foss, 1949-68
William J. Kinnard, Jr., 1968-

(NOTE: Figure in parentheses following name indicates year of graduation from Maryland College of Pharmacy or University of Maryland.)



Congratulations Lynette!

ASP President and MPhA Trustee Lynette Bradley was one of four students nationwide who were selected to receive a \$2,000 scholarship from the 1991 APhA/Glaxo Good Government Scholarship Competition. Lynette's winning entry, which outlined a course to teach pharmacy students about pharmacy, government and public affairs will be featured in an upcoming issue.

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The Maryland Pharmacist **MAY 1991**

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by September 30, 1991. A continuing education certificate for one contact credit will be mailed to you within 30 days. Please type or print clearly.

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Nocturnal Leg Cramps

1. Q-vel Softgels differ from most other OTC products for treatment of nocturnal leg cramps in that the former contains quinine plus:
 - a. aspirin.
 - b. diphenhydramine.
 - c. vitamin E.
 - d. ascorbic acid.
2. All of the following mechanisms of action are suggested for quinine in alleviating leg cramps EXCEPT:
 - a. lengthening motor end plate excitability.
 - b. decreasing the response of muscle to electrical stimulation.
 - c. lengthening of the muscle refractory period.
 - d. decreasing the response of muscle to mechanical stimulation.
3. Which of the following beverages is consumed by some individuals to help relieve nocturnal leg cramps?
 - a. Club soda
 - b. Coffee
 - c. Cola drinks
 - d. Tonic water
4. Symptoms of quinine overdose are referred to collectively as:
 - a. bromism.
 - b. cinchonism.
 - c. Parkinsonism.
 - d. Cushings.
5. Of the following dosage regimens, which is correct for quinine taken for nocturnal leg cramps?
 - a. 30 mg four times a day with meals and at bedtime.
 - b. 130 mg after the evening meal and at bedtime.
 - c. 260 mg mid-day and at bedtime.
 - d. 500 mg at bedtime, with a snack.
6. Of the following, the most prevalent side effect associated with quinine is:
 - a. drowsiness.
 - b. gastrointestinal upset.
 - c. insomnia.
 - d. nocturnal enuresis.
7. All of the following products are marketed OTC for relief/prevention of nocturnal leg cramps EXCEPT:
 - a. Duraquin.
 - b. Quine.
 - c. Legatrin.
 - d. Q-vel.
8. All of the following are reported causes of nocturnal leg cramps EXCEPT:
 - a. arterial contractions.
 - b. lactic acid accumulation.
 - c. muscle anoxia.
 - d. venostasis.
9. When counseling consumers on OTC products for relief/prevention of nocturnal leg cramps, it should be kept in mind that all of the following are warning signs that the product should be discontinued and a physician contacted, EXCEPT:
 - a. blurred/double vision.
 - b. congested/runny nose.
 - c. nausea/vomiting/diarrhea.
 - d. ringing/buzzing in the ears.
10. Which of the following profiles of electrolyte imbalance is reportedly a precipitating factor for nocturnal leg cramps?
 - a. Hyperkalemia and hypernatremia
 - b. Hyperkalemia and hyponatremia
 - c. Hypokalemia and hypernatremia
 - d. Hypokalemia and hyponatremia

Classified

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The Maryland Pharmacist

VOL. 67

June, 1991

No. 6



*MPhA Completes Another
Successful Legislative Session*



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The Maryland Pharmacist (ISSN 0025-4347) is published monthly by the Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201. Annual Subscription — United States and foreign, \$10 a year; single copies, \$1.50. Members of the Maryland Pharmacists Association receive The Maryland Pharmacist each month as part of their annual membership dues. Entered as second class matter at Baltimore, Maryland and additional mailing offices. Postmaster: send address changes to: The Maryland Pharmacist, 650 West Lombard Street, Baltimore, Maryland 21201.

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On The Road

It has been stated that we can be on the right track, but unless we go forward, we will get run over. I am here to tell you that we *are* on the right track and we will not get run over.

We have accomplished a great deal over the last year.

In the legislature we have laid the ground work for our second freedom of choice law—this time focusing on the unfair and exclusive pharmacy networks many HMOs have created. It is now just as illegal for a physician to employ a pharmacist as it is for a pharmacist to work for a physician. We have had legislation passed giving pharmacists' legal authority to dispense unauthorized refills in a declared state emergency crisis.

In the courts, we stopped attempts by Blue Cross to capture any part of our professional fee and defended AWP as a cost basis for their program. Thanks to efforts by MPhA, our Medicaid professional fee increases by 25 cents on July 1, 1991. The Maryland Pharmacist Association is also being consulted by the State on a wide variety of issues.

Any of the above accomplishments could have led us to a successful year, but we have also laid the ground work for the strengthening of our profession in Maryland. The Long Range Planning Committee has met and now plays an active role in developing MPhA goals and activities for the future. This committee has already developed a new mission statement and identified strategic long term and short term objectives.

The Professional Affairs Committee is now working to define the standards of practice for pharmacy; not only standards for the care of patients and customers, but also standards that send a message to the insurance and benefits managers that pharmacy that fails to meet these standards is unacceptable in Maryland.

The Constitution and Bylaws Committee has also been very active and is presenting a complete revision of our bylaws highlighted with the expansion of the Board of Trustees so that the Board will reflect the way pharmacy is practiced in Maryland.

As with any administration, there were some goals not reached, but hopefully the Maryland Pharmacists Association is better off today than it was in June of 1990.

Last, but not least, I want to thank the Board of Trustees and the many volunteers who served on MPhA committees—all of you so willingly gave of your time to create a better MPhA. To David Miller and his staff, I wish the best and thank them for all their help. Finally, I would like to say thanks for the memories.

Mark A. Levi, P.D.

President

Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Counseling Consumers on Dry, Chapped, and Sun Damaged Lips

by Thomas A. Gossel, R.Ph., Ph.D.
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and Toxicology
Ohio Northern University
Ada, Ohio

and

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Goals

The goals of this lesson are to:

1. discuss various self-treatable conditions of the lips, and, when appropriate, differentiate them from serious medical pathologies; and
2. present current thought on the management of these afflictions with OTC products.

Objectives

At the conclusion of this lesson, the successful participant should be able to:

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1. identify the various lip conditions and explain their similarities and differences;
2. choose how to best prevent and self-treat common disorders of the lips;
3. demonstrate an understanding of the ingredients of OTC lip care products, as well as their actions, uses and limitations; and
4. choose from a list, important information to convey to consumers who wish to self-treat conditions of the lips.

Almost everyone has experienced the agony of dry, chapped, or irritated lips. Such afflictions can occur year round. They are most common during winter months. Men apply OTC lip balms or other soothing cream or emollient products on their lips to improve comfort. Although women obtain some measure of protection from lipsticks, they also seek added comfort and relief with OTC lip balm products.

Studies have shown that OTC lip protection products have sales appeal as impulse items. They are, therefore, often displayed at pharmacy and grocery checkout counters. Their sales traditionally rank high among OTC topical products for skin care sold in pharmacies in the U.S.

This lesson summarizes common causes of lip discomfort. It lists means to self-treat various disorders of the lips, and concludes with important points of information to convey to consumers who inquire about lip care and appropriate OTC products.

Common Lip Disorders

Dry, Chapped, and Sunburned Lips. While the lips (like other transitional tissue such as the nostrils, conjunctiva, nipples, external genitalia and perianal area) are continuous with the skin and the body's mucous membranes, they are susceptible to drying, sunburn, and chapping. Unlike the skin, lips do not contain a significant number of melanocytes, the cells that produce melanin (the body's sunscreen). They do not tan, but can be easily burned by solar ultraviolet (UV) light.

Lips also contain numerous nerve endings which are important to an individual's personal gratification when touching another person. These same nerve endings also account for the discomfort felt when lips become dry, chapped, or irritated. Because of this uncomfortable sensation, the affected person may unconsciously and uncontrollably, but constantly, wipe or lick, or bite or pick at the lips, thus continuing to perpetuate the damage.

Also unlike skin, lips do not contain sweat or sebaceous glands to keep them moist. This is why some persons repeatedly lick their lips. When licked excessively, especially when the lips are dry, they can become even drier and more irritated.

The lips are prone to drying and cracking during all months of the year. But, lip damage is especially critical during the winter. Relative humidity is low in winter resulting in injury to the lips due to a combination of cold air and whipping winds. This is especially true for the northern states and dry western regions. The low moisture content characteristic of winter air translates to a very dry relative humidity when the air is warmed inside buildings.

Relative humidity, recall, represents the percentage of moisture in the air compared to the total amount (absolute) that it can actually hold at that temperature. The lips can lose mois-

ture to the environment in artificially warmed air. Warm air holds more water than cold air. Therefore, the amount of moisture that indoor, heated air needs to maintain a comfortable relative humidity cannot be adequately supplied by outside cold air which is then heated by a furnace. The result is loss of moisture by skin and other transitional tissue, such as the lips.

Sun can also damage the lips as much during the winter months as during summer. The dry, cold winter air, combined with a snow layer to reflect solar UV rays, may be especially detrimental to lip health. This unexpected damage to the lips may take an individual by surprise.

The higher the altitude, the more intense is the potential for sun-induced lip damage. An increase in altitude of 1000 ft intensifies the extent of solar damage by four percent. At an altitude of 6000 ft above sea level there is, therefore, a 24 percent greater intensity of UV light than at sea level.

Added to this is the snow's ability to reflect the sun's rays. Snow can reflect up to 90 percent of solar rays. Reflected rays can damage the upper lip even more than the lower one, for the upper lip is not shaded from the reflected rays of the sun. So a ski lodge atop a mountain peak may be a prime location to acquire sunburned lips, or potentiate damage caused by the dry air and chilling wind. Because of all these combined factors, reflected UV light damage can be even more intensive than that experienced in summer.

UV Light and Skin Cancer. Lip cancer is the most common malignancy of the oral mucosa. Lesions typically measure 1 mm or less in diameter, and traditionally occur on the vermilion (red) surface of the lower lip. The lower lip is usually more directly exposed to sunlight. Moustaches, and perhaps even a large nose, may help shade the upper lip.

The primary etiologic factor in promoting lip cancer is accumulated UV irradiation from the sun. This fact may help explain why the lower lip is more susceptible to malignant sun damage. Most sufferers of lip cancer have outdoor occupations such as farming or commercial fishing.

Ninety-five percent of respondents with lip cancer in one study admitted that their skin burned easily. Sixty-two percent also related a life-long history of serious sunburn. Reassuringly, lip

carcinoma is usually well differentiated, thus easy to detect, and slow to metastasize. Cure rates of 90 percent at five years are common.

Pipe smoking is believed to be a cause of lip cancer because it exerts constant mechanical and thermal irritation to the site on the lips where the pipe is held. However, pipe smoking alone is probably not an important cause. If it were, the trauma would not necessarily be confined to the lower lip. Also, lip cancer is rare in Blacks who smoke pipes, and the proportion of pipe smokers among patients with lip cancer varies considerably in different studies. However, pipe smoking most likely aggravates solar-induced damage, and it is linked to other types of oral cancer.

An ulcer, sore, blister or cold sore that doesn't go away is the type of initial lesion of lip cancer that most affected people report. A persistent roughness of lip tissue, with concurrent crusting or scab formation as the initial lesion, is another symptom sometimes reported.

Treatment of Lip Disorders With OTC Products

Dry, Chapped, and Sunburned Lips. Many of the basic principles that pertain to management of dry skin also apply to dry, chapped, and irritated lips. Some OTC products available for

treatment of dry skin *per se* are not suitable for dry lips because they are too easily removed by licking the lips, or because they taste unpleasant.

A **skin protectant** is an agent which protects injured or exposed mucous membrane surfaces from harmful or annoying stimuli. A **lip balm** is defined as a drug product that relieves and prevents dryness or chapping of the exposed surface of the lips.

Lip balms and skin protectants are usually ointments. Products formulated as "**chap sticks**" are solid bars of petrolatum and waxes. They may also contain other skin protectants. Their wax base imparts a solid consistency to the product suitable for applying it in the solid form of a lipstick.

Any of these products are suitable for treating dry, chapped, or irritated lips. Many lip care products also contain local anesthetics, camphor, phenol, menthol, or a sunscreen agent.

The following OTC product ingredients are safe and effective (i.e., Category I) for treatment of dry, irritated, chapped lips: allantoin, cocoa butter, dimethicone, glycerin, petrolatum and white petrolatum, and shark liver oil. Most OTC lip care products (Table 1) contain one or more of these drug agents.

Again, many other soothing ointments, and occlusive, hydrophobic substances, will provide relief to irritated lips. Their limitations are their

Table 1
Representative OTC Lip Protectant Products

Product (Mfr)	Form	Ingredients
Blistex Lip (Blistex)	Ointment	Camphor 0.05%, Phenol 0.5%, Allantoin 1%
Carmex (Carma Labs)	Ointment	Petrolatum*, Lanolin*, Cocoa butter*
ChapStick (Robins)	Stick	Petrolatums 44%, padimate 1.5%, Lanolin 1%
Herpecin-L (Campbell Labs)	Lip balm	Pyridoxine HCl*, Allantoin*, Padimate O*, Titanium dioxide*
Lip-Gard (Whitehall)	Lip balm	Live yeast derivative containing skin respiratory factor 67 U/gm, homosalate 5%
Tanac (Commerce)	Stick	Benzocaine 7.5%, tannic acid 6%, octyl dimethyl PABA 0.75%
Tanac (Commerce)	Liquid	Benzocaine 10%, Tannic acid 6%
Vaseline Pure Petroleum Jelly (Chesebrough-Ponds)	Gel	White petrolatum 100%
Vaseline Constant Care (Chesebrough-Ponds)	Stick	Petrolatum*, Paraffin*

*Concentration not specified

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Table 2

Representative OTC Lip Sunscreen Products

Product (Mfr)	SPF*	Ingredients
Blistik Lipbalm (Blistex)	10	Padimate O 6.6%, oxybenzone 2.5%, Dimethicone 20%
Blistik Daily Conditioning Treatment (Blistex)	12	Padimate O 7.5%, oxybenzone 3.5%
Chap et Sun Ban (Stanback)	15	Padimate O 7%, oxybenzone 3%
ChapStick Sunblock (Robins Consumer)	15	Padimate O 7%, oxybenzone 3%
Daily Conditioning Treatment (Blistex)	12	Padimate O 7.5%, oxybenzone 3.5%, petrolatum**
Eclipse Lip and Face Protectant (Herbert)	15	Padimate O**, oxybenzone**
Hawaiian Tropic Lip Balm Sunblock (Tanning Research)	15	Padimate O**, oxybenzone**
Lipkote by Coppertone (Plough)	15	Padimate O**, oxybenzone**
Mentholatum Lipbalm (Mentholatum Co)	14.7	Octyl dimethyl PABA 8%, petrolatum**
PreSun 15 Lip Protector (Westwood)	15	Padimate O 8%, oxybenzone 3%
RVPaba (Elder)	10	PABA 5%, red petrolatum**
Vaseline Lip (Chesebrough-Ponds)	15	White petrolatum**, padimate O**, oxybenzone**

*Sun Protection Factor

**Concentration not specified

poor substantivity on the lips, formulation difficulties, and unpleasant taste.

Sunscreen Lip Products. An ideal sunscreen should (1) protect the lips against sunburning, regardless of climate, (2) maintain protection throughout the period of normal usage, (3) be nonirritating, nonsensitizing, and non-toxic, (4) be cosmetically elegant, (5) be resistant to removal by licking or biting, and (6) be stable. Products for application to the lips should also have a pleasant taste. While no single sunscreen is ideal for all persons, the currently marketed OTC products (Table 2) provide the most effective protection against sun-induced damage to the lips.

Sunscreen lip products protect tissue from damage via one of two mechanisms. The first group, represented by chemical sunscreens such as *p*-aminobenzoic acid (PABA), padimate O, or oxybenzone, act by filtering and absorbing UV light in the 290-320 nm (nanometer; 10⁻⁹ meter) range. They consequently reduce the total amount of UV light that penetrates down to the lips' mucosal surfaces.

The second group, physical sunscreens (sun shades) such as red pet-

rolatum, titanium dioxide, and zinc oxide, are opaque formulations that deflect or scatter the sun's rays. This prevents toxic amounts of solar radiation from reaching the skin. Their major disadvantage is that they are physically uncomfortable and cosmetically unacceptable to many persons for application to large areas. However, they are useful for protecting limited areas of extreme vulnerability, such as the lips.

The product's active ingredients and vehicle are major factors that influence the effectiveness and duration of sunscreen or sun blocking agents on the lips. All sunscreens afford some degree of protection; PABA and its esters display superior protection in most tests when they are compared to other agents.

Sunscreens are normally safe for repeated, continuous use. PABA and its esters occasionally cause allergic contact dermatitis. One study reported a phototoxic reaction resembling severe sunburn, when a product containing amyldimethyl PABA was used. Cross reactivity has also been reported between PABA and its esters, with benzocaine, aniline, sulfonamides,

thiazides, and *p*-phenylenediamine. At present, most evidence suggests that increased or decreased sensitivity of the lip mucosa to repeated exposure of sunscreen products is rare.

Sunscreens should be applied 45 to 60 minutes before exposure to the sun. They should also be reapplied freely after swimming or sweating, and at least hourly throughout the period of exposure to sunlight. One investigation revealed that patients with lip cancer that appeared later in life, were active in the sun during ages 20 to 30 years. The cancer appeared after a latent period of another 20-30 years, suggesting that repeated exposure to the sun is needed before significant damage will occur.

It is more difficult to maintain a therapeutic level of protectant product on the lips, than on most other dermal surfaces. Consequently, the vehicle is especially important to lip care products. This is particularly relevant if the substance has an unusual or unpleasant "feel", or a disagreeable taste. Many creams and some wax-based products may be messy and objectionable to use. The individual may consciously, or unconsciously, lick or bite at the lips and quickly remove the product.

Lip Tips: Counseling Consumers on Their Care

Many OTC products which are intended for use on the lips are indicated to treat a wide variety of lip afflictions. These may include providing relief of dry and chapped lips and recurrent cold sores, and protecting against damage from the sun. Other lip care products are labeled for more limited indications.

Regardless, any product specifically intended for use on the lips will probably afford relief from most self-treatable conditions. Since the lips do not have sweat glands, and the effective use of lip balms is to moisturize lip tissue, the person should moisten the lips before applying the products.

Patients who take prescription or OTC drugs that cause drying of the skin and lips should be counseled to consider purchasing a lip protection product. Causative drugs that irritate the lips include Accutane and Tegison, anticholinergics, and antihistamines. Too often, pharmacists forget to use this type of coupling advice that not

Table 3**Consumer Information on OTC Lip Care Products****Lip Balms**

- This product soothes dry, chapped, or irritated lips, and may also provide some protection against sunburn. If uncertain whether it will effectively protect against sunburn, ask your pharmacist.
- Apply this product to your lips at least once every hour, or whenever needed. A thin layer should be sufficient. Wet your lips before applying. Do not bite at your lips or lick the product off.
- If your chapped lips fail to get better within 7 days, or they continue to get worse, see a doctor.

Lip Sunscreens

- Apply this product on your lips any time they are exposed to sunlight, during the winter or summer.
- Use this product on your lips at least once every hour while you will be in the sun. Apply the first application 45 to 60 minutes before exposure to the sun. Wet your lips before applying the product. Do not bite at your lips or lick the product off.
- Apply this product liberally, before and after swimming, eating and drinking, and during other activities that remove it from your lips.
- If your lips become red or inflamed while using this product, stop using it. If irritation continues or worsens, see a doctor.
- Avoid exposure to sunlight. Wear a wide-brimmed hat, and use a sunscreen product on your lips whenever you will be exposed to sunlight.

General Advice

- Drink at least 6 to 8 glassfuls of liquid each day to help restore moisture to your lips.
- Cover your lips with a scarf when outside in chilling winter air. Protect them from direct and reflected rays of the sun.
- If your home or workplace does not have a central humidifier system, consider using portable units to add moisture to your environmental air.
- If you have questions about whether your lips are irritated because they are dry, or damaged by the sun or other environmental causes, or are irritated by a fever blister or canker sore, ask your pharmacist or doctor for advice.

only can increase the economic health of the pharmacy and capture back some of the OTC sales that have been lost to non-pharmacy outlets, but more importantly provides greater patient comfort — a prime goal of the profession.

Consumers may not be fully aware of the importance of protecting the lips from the sun, especially during the chilling winter months. In the warm months, they may freely apply a sunscreen product elsewhere on their body, but fail to apply it to their lips because of their lack of knowledge of the importance to do so.

Standard sunscreen products for the skin may provide partial protection to the lips when applied. While these products are formulated with perfumery scents to make them pleasant to smell, they are not manufactured with palatability in mind. Also, they may

have poor substantivity (the ability to remain on the skin after swimming or sweating).

It is important for children to use lip balms when they play in the sun or in cold weather. Parents should be more sensitive to their needs in this area. The best way to treat chapped lips and split corners of the mouth in children is to prevent them from occurring in the first place.

Consumers may be sensitive to sunscreens such as PABA, or to local anesthetics such as benzocaine. Affected persons should be advised to avoid use of products containing these ingredients.

OTC lip balm products must be labeled to warn users that if the condition worsens or does not improve within 7 days, to consult a physician. The 7-day limitation is not related to adverse effects of the product; OTC lip

care products can be safely used for indefinite periods.

The limitation is to alert consumers that dry, chapped or irritated lips can be caused by pathologies and nutritional deficiencies which, if left undiagnosed and untreated, can be harmful. Such conditions include cheilosis (serious inflammation of the lips), ichthyosis vulgaris (a defect in the horny layer of lip tissue that causes scaling and a "fishskin" appearance), xeroderma (excessive dryness due to an increase in the horny layer of lip tissue), herpes infections, and lip cancer.

The points listed in Table 3 pertain to OTC lip care products and self-treatment of chapped lips. They can be conveyed to consumers who purchase them.

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1991 Legislative Wrap-Up

Robin Shaivitz, Legislative Consultant

The 1991 Session of the General Assembly may have been slower overall, but that was not true for pharmacy issues. This year, a variety of issues were raised that covered just about every aspect of the profession of pharmacy.

One of our biggest successes this session was a 25 cent increase in the medicaid dispensing fee. Although the increase was years overdue, given the tight budget situation, we were never sure until the budget was put to bed on April 1, that the fee would remain intact. Fortunately, it did remain and will go into effect on July 1, 1991.

Another payment issue, the pharmacy co-payments was negotiated until the very last moments of the session. The bill went to a conference committee, was filibustered and passed with literally only minutes to spare. The five dollar increase survived with the stipulation that it would be studied in order to possibly reduce the amount to something under five dollars.

We should be very pleased that our trilogy of bills introduced by Delegates Elliott and Bozman passed relatively early in the session. Although HB 118 and HB 119 proved non-controversial, we did need to convince Senator Hollinger that HB 112, Disciplinary Grounds for physicians who hired pharmacists, was indeed in the best interests of both groups of health care professionals and the public as well.

During the Session, the bill that caused the greatest concern was SB 193, Triplicate Prescription. The bill was heavily lobbied on both sides, with the Drug Enforcement Agency principally pushing a serialized prescription program (the amended bill) and a coalition of providers, third-party payors and pharmaceutical manufacturers in opposition. The opponents of the bill prevailed. The bill, having reached the floor of the Senate, was recommitted to the Economic and Environmental Affairs Committee for further work. The Committee plans to study the issue during the interim. MPhA plans to work with the coalition to develop a proactive approach that we can present to the Legislature for discussion.

Finally, Delegate Weir introduced a Freedom of Choice bill for pharmacy. Although it did not pass the Environmental Matters Committee, it generated a great deal of support. The issue will be studied, along with other HMO-related matters during the Fall. It will be studied jointly by Environmental Matters and Eco-

nomic Matters since the subject matter really overlaps both Committees' jurisdictions.

The pharmacists are to be congratulated for another outstanding year. Our early planning and preparation plus our membership's quick response to calls for action contributed to our success. I thoroughly enjoyed working with you, once again.

What follows is a list of the final status of the legislation in which you had an interest.

Legislative Analysis and Strategy

1991 House Bills

House Bill 112

Physicians—Operation of Pharmacies—Disciplinary Grounds

Sponsor: Elliott, Bozman

Position: support

Prohibits physicians from entering into a relationship with a pharmacist for the purpose of owning a pharmacy. Provides for disciplinary action against physicians found guilty of such.

Final Status: Passed

House Bill 118

Pharmacists—Unauthorized Refills—Declared Emergencies

Sponsor: Elliott, Bozman

Position: support

Enables a pharmacist to dispense up to a 7 day supply of medication on an unauthorized refill when a state or national state of emergency has been declared.

Final Status: Passed

House Bill 119

Pharmacies—Reference Libraries

Sponsor: Elliott, Bozman

Position: support

Removes the requirement for a USP/NF in every pharmacy licensed in Maryland. Establishes in statute a requirement that there be a reference library in each pharmacy suitable to the practice.

Final Status: Passed

House Bill 173

Anabolic Steroids

Sponsor: Department, Ehrlich, Rosenberg

Position: oppose

Reschedules all anabolic steroids and human growth hormone to Class III. Penalty for improper prescribing, dispensing or possession is a misdemeanor instead of a felony. Requires a sign to be posted in athletic facilities stating this fact.

Final Status: Passed

House Bill 255

Health Occupations Boards—Omnibus Bill—Administrative Review

Sponsor: Guns (for Department)

Position: oppose

Would enable the Board of Pharmacy, and all other licensing Boards, to appeal any order that modifies or reverses a previous Board decision.

Final Status: Killed

House Bill 294

Health Maintenance Organizations—Prompt Payment of Claims

Sponsor: Guns (for Department of Licensing & Regulation)

Position: support

Requires an HMO to pay any provider claim within 30 days. If the claim is not paid within that time period, the HMO shall pay 1.5% simple interest per month as well as prorated for any portion of a month. Does not apply when a claim is in dispute.

Final Status: Killed (See Senate Bill 317/sister bill)

House Bill 342

Health Care Utilization Review

Sponsor: LaMotte, Thomas, Teitelbaum, Pitkin, Perry

Position: monitor only

Requires private PRO organizations to have policies and procedures to ensure that a representative of the PRO be available 24 hours a day 7 days a week in Maryland. Permits an appeal process for providers and patients. Permits the Secretary to set up guidelines for health care utilization review.

Final Status: Passed

House Bill 409:

Health Occupations Boards

Sponsor: Thomas (Chair, Sunset Evaluations)

Position: oppose, amend line 5, page 14 to "Pharmacists"

Permits for the removal of Board of Pharmacy (and other Boards) members if they have missed two Board meetings. Permits the Governor to appoint any vacancy on the Board within 60 days of the vacancy. Includes language that would permit residents of Maryland other than MPhA to submit names for candidacy to the Governor for appointment. Bill identifies MPhA as "Maryland Pharmaceutical Association."

Final Status: Kill

House Bill 416

Health Maintenance Organizations—Prompt Payment of Claims

Sponsor: LaMotte

Position: support

Requires an HMO to pay any provider claim within 30 days. If the claim is not paid within that time period, the HMO shall pay 1.5% simple interest per month as well as prorated for any portion of a month. Does not apply when a claim is in dispute.

Final Status: Passed

House Bill 487

Department of Health and Income Security

Sponsor: Mitchell (for Administration)

Position: monitor only

Amend page 51, line 6 to "Pharmacists"

Creates a Department of Health and Income Security by transferring medical care programs and family care programs from the Department of Health and Mental Hygiene. Does not explain what happens to the licensing Boards. Contains information on the Medical Assistance and Pharmacy Assistance programs but there are not changes in the language. Bill identifies MPhA as "Maryland Pharmaceutical Association."

Final Status: Killed

House Bill 618

Health Insurance—Interest on Reimbursement

Sponsor: Taylor

Position: support

Increases the amount of interest that made be charged on late payments from health insurers to 1.5 percent 31 to 60 days after a proper claim has been filed, 2 percent from the 61st day to the 90th day, and 3 percent after the 91st day.

Final Status: Passed

House Bill 634

Health Maintenance Organizations—Managed Care Plans

Sponsor: Taylor

Position: monitor only

Requires that to qualify as a health maintenance organization, a plan must have a managed care program in place.

Final Status: Killed

House Bill 651

Medical Assistance Program—Managed Care Program Termination

Sponsor: Jeffries, Montague, Anderson, Kirk, Parham, Jones, Cummings, Davis, Fulton, Kelley, Marriott

Position: support

Requires the Maryland "Access to Care" program to have a sunset of June 30, 1993 and support a report to the Assembly demonstrating that it has not adversely affected health care of recipients and has resulted in actual savings.

Final Status: Passed

House Bill 660

Health Maintenance Organizations—Subscriber Liability

Sponsor: Littrell, Gary

Position: support

Requires all HMOs to provide information to subscribers that they are liable for any charges incurred with providers who do not have written contracts with the HMO.

Final Status: Killed

House Bill 728

Controlled Dangerous Substances Tax

Sponsor: Littrell

Position: monitor only

Taxes sales of CDS except for pharmacists, physicians, etc. Designed to have another way to charge drug dealers because they have failed to collect a tax.

Final Status: Killed

House Bill 783

Maryland Pharmacy Assistance Program—Copayments

Sponsor: Department

Position: support

Increases Pharmacy Assistance copay to \$5.00. Limits covered drugs to anti-infectives and maintenance drug list developed by the Department and MPhA.

Final Status: Passed with last minute changes

House Bill 789

Health Manpower Shortage—Incentive Grants

Sponsor: Kopp, Gordon, Davis, Heller

Position: support

Provides state assistance for grants to students in certain health professions for tuition, etc. Pharmacy is included.

Final Status: Passed

House Bill 842

Maryland Medical and Pharmacy Assistance Program—Provider Tax

Sponsor: Department

Position: support

Allows Department to collect additional "tax" to increase the Federal matching funds.

Final Status: Passed

House Bill 876

Health Occupations—Disciplinary Grounds—Sexual Intimacy

Sponsor: Teitelbaum, McHale, Perry, Heller

Position: monitor only

Permitting action against health professionals by the licensing boards for engaging in sexual intimacy for any current or former patient. Does not affect Board of Pharmacy.

Final Status: withdrawn

House Bill 1143

Council of Allied Health Professionals

Sponsor: DiPietro

Position: oppose

Creates a Board of Allied Health Professionals empowered to grant certification and/or licensure to allied health practitioners like pharmacy technicians and physician assistants without going to the health board that regulates that particular profession.

Final Status: Killed

House Bill 1191

HMOs—Pharmaceutical Services

Sponsor: Weir, LaMotte, DiPietro

Position: support

Requires HMOs to accept any pharmacy as a provider who will agree to accept the HMOs' reimbursement terms.

Final Status: Referred to Summer Study

House Bill 1210

CDS—Colored Coded Prescription Pads

Sponsor: Kolodziejski

Position: oppose

Requires all controlled substance prescriptions to be written on a specific colored prescription pad.

Final Status: Killed

House Bill 1263

HMOs—Payment for Referral Services

Sponsor: Wood

Position: support

Requires HMOs to pay all provider claims under a contract signed by another when the other has contracted with or referred patients to the provider.

Final Status: Passed

1991 Senate Bills

Senate Resolution 11

Commission on Drug Policy Reform

Sponsor: Lapides, Boozer, Hughes

Position: support

amend language from "Maryland Association of Pharmacists" to "Maryland Pharmacists Association"

Creates a Commission to study costs and effectiveness of the present drug law policies.

Final Status: Killed

Senate Bill 154

Health Care Facilities—HIV Testing—Surgical Patients

Sponsor: Murphy

Position: monitor only

Requires testing of patient's blood for HIV under certain circumstances upon entry into a health care facility and for the facility to inform the patient that their blood will be tested.

Final Status: Killed

Senate Bill 156

HIV—Health Care Providers—Exposure

Sponsor: Murphy

Position: monitor only

Requires testing of patient's blood for HIV under certain circumstances when a health care provider may have been exposed.

Final Status: Passed

Senate Bill 169

Health Care Practitioners—Referral of Patients

Sponsor: Hollinger, Collins, Dorman, Garrott, Lawlah

Position: support

Would prohibit a provider from directing a patient to a health care facility or service, including a pharmacy, in which the provider or their immediate family has a significant financial interest. An exception is made if the provider discloses the relationship in writing to the patient, requires a written receipt from the patient acknowledging the information, and states that the patient

may choose to obtain the health services from another provider.

Final Status: Passed

Senate Bill 193

Triplicate Prescriptions

Sponsor: Lapides, Winegrad, Smelser, Garrott, Haines,

Lawlah, Foster

Position: oppose

Requires a triplicate prescription system be adopted by the Department of Health and Mental Hygiene. It is expected that a significant financial note will be attached to this bill. Additionally, the bill is redundant in light of the efforts being made by the Governor's Prescription Drug Commission.

Final Status: Killed

Senate Bill 271

Medical Assistance Program—Managed Care Program—Providers

Sponsor: Young, Trotter

Position: support, with amendments

Requires Medicaid recipients the right to change providers in the proposed Maryland Access to Care (MAC) program within 30 days of first visiting the provider. This allows the patient who doesn't want to belong to an HMO the opportunity to get out *after* having visited the HMO once.

Final Status: Killed

Senate Bill 316

Interdepartmental Committee on Mandated Health Benefits

Sponsor: Sher, Bromwell

Position: monitor only

Enables the Interdepartmental Committee on Mandated Health Insurance Benefits to conduct reviews of non-discrimination provisions.

Final Status: Passed

Senate Bill 317

Health Maintenance Organizations—Prompt Payment of Claims

Sponsor: Sher

Position: support

Requires an HMO to pay any provider claim within 30 days. If the claim is not paid within that time period, the HMO shall pay 1.5% simple interest per month as well as prorated for any portion of a month. Does not apply when a claim is in dispute.

Final Status: Passed

Senate Bill 412

Health Manpower Shortage Incentive Grant Proposal

Sponsor: Hollinger, Young
Position: support as amended to include pharmacy

Includes pharmacy in a list of health professionals for whom state educational grants would be available for financial aid.

Final Status: Passed

Senate Bill 493

State Health Benefit Programs—Limitation of Coverage
Pharmaceutical Products

Sponsor: Young, Hoffman, Hollinger, Bromwell,
Boozer, Hafer
Position: support

Requires pharmaceutical manufacturers to provide the same rebates to Maryland Medicaid—State Only, Pharmacy Assistance, and the State Employee Prescription Drug Program and if not to allow those programs to limit coverage of those manufacturers' drugs. [PAPPA for the state!]

Final Status: Killed

Senate Bill 633

Health Insurance—Payment of Claims—Notice

Sponsor: Murphy, Boozer, Bromwell

Position: support

Requires health plans and insurers to provide a notice within 15 days of a claim submission that the claim is going to be paid, turned down, and acknowledging receipt. Also provides for interest penalties on non-paid claims.

Final Status: Passed

Senate Bill 699

Health Maintenance Organizations—Managed Care
Plans

Sponsor: Bromwell

Position: monitor only

Requires HMOs and certain health plans to have a managed care program to get permission to operate and how the managed care plan shall be set up.

Final Status: Killed

Senate Bill 701

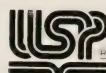
Health Maintenance Organizations—Subscriber Liability

Sponsor: Bromwell, Wagner and Young

Position: monitor only

Requires HMOs to provide information to their patients that they may be liable for charges if a provider is not under written contract with the HMO.

Final Status: Passed



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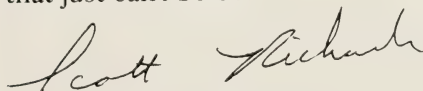
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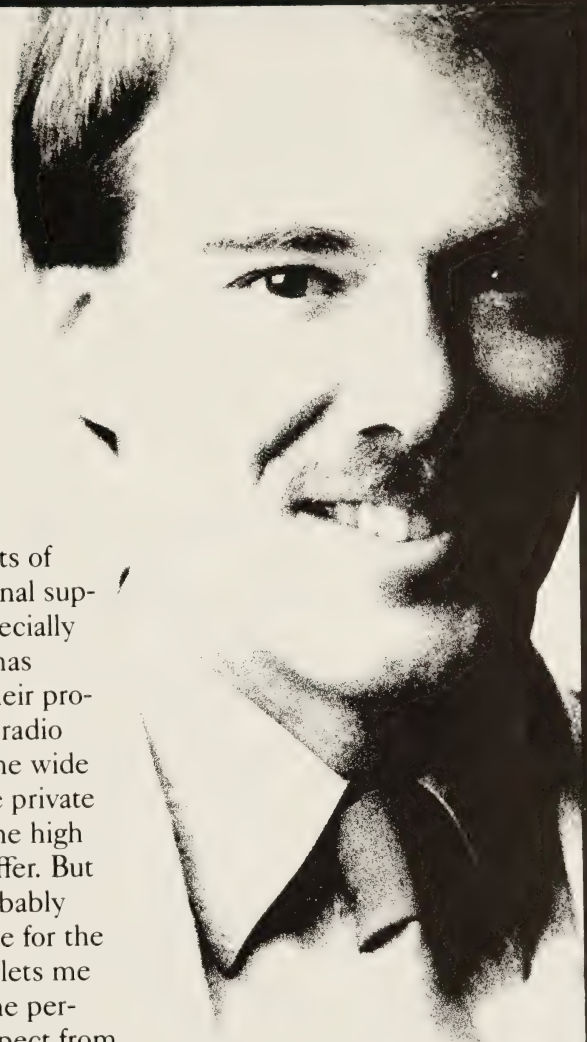
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An Elective Course to be devised and offered at the Undergraduate level to promote student involvement in pharmacy government and public affairs

Lynette R. Bradley

The beginning of pharmacy students participation in the field of pharmacy originates at the undergraduate level. As students' minds engulf all the pharmacology, toxicology, laws and other facts that will lead to the desired pharmacy degree and license, the issue of governmental and legislative involvement in pharmacy tends to be overlooked and quite often ignored. Therefore, a plan of action to promote student government/public affairs participation would be to create a course at the undergraduate level that would be available to pharmacy students at accredited schools of pharmacy.

This course would be offered as an elective so that only the students genuinely interested in exploring and learning about accurate governmental procedures and regulations as it relates to pharmacy would elect to take it. It would be open to all stu-

dents and would prove to be especially beneficial to the leaders of pharmacy student organizations such as the Academy Students of Pharmacy (ASP). This course would enable students to guide their organizations and lives to a more efficient and productive atmosphere as good organizational skills, procedures and governmental aspects would be discussed and emphasized.

The first objective of this elective course would be to teach the basic regulations and procedures of general government. Review of basic legislative, executive and judicial qualities on the federal, state and local levels would be done. In order to be coherent and involved in pharmacy related issues that involve governmental aspects, a knowledge of the "backbone" of the government is essential.

Once the basics are taught, the involvement in government related to pharmacy are to be explored. The students would be exposed to current pharmacy related laws, procedures and issues. There are various methods in which students can learn about policy decision making, pharmacy governmental regulations and public affairs involvement. It is at this point where the program can vary from school to school—a school can determine to accept one of the three aforementioned methods to promote students learning and involvement.

The method of learning about pharmacy policy decision making can be done in a multitude of ways. Speakers from state and national pharmacy organizations could be invited to deliver speeches discussing how policies evolve from a single pharmacist's idea all the way to a national forum. Opportunities for students to intern and work for state associations should also be available to those who are interested in being directly involved in policy making by working side by side with those who are an integral part to the actual process. The class as a unit or on an individual basis could devise and propose policies to be sent to the state level and can become involved in the lobbying and other procedures needed to bring the policy to the national/federal level. These as well as other ideas can be created and implemented to teach and involve students in pharmacy policy decision making.

Students could also learn about the formation, implementation, and carrying out of pharmacy governmental regulations in various fashions. Speakers from various pharmacy organizations on the state and federal levels could speak on how pharmacy regulations are developed from the bottom up and how students could become involved in this process. Additional minicourse series on thinking of and planning new possible regulations based on cur-

rent concerns or problems related to pharmacy could also be started. The ideas stated previously in developing knowledge in policy decision making can also be performed for pharmacy governmental regulations.

The involvement of pharmacists in public affairs is a growing phenomenon as pharmacists see the need for closer ties with the general public. Thusly, students can start in school to become aware of the important role a pharmacist can play in bringing awareness of a variety of health related issues and concerns to the public. The students as a unit or as individuals could develop and talk about a health related concern or problem that would provide accurate information to the people. Such issues to be researched and discussed include AIDS and prescription drug addiction. The course should not only stress the importance of pharmacy regulations and policy decision making, but should also emphasize that public affairs concerns can and the majority of the time does directly effect the control of pharmacy and its regulations.

A school may decide not to choose a specific aspect to follow—they may decide to make the course to include all three aspects of pharmacy policy decision making, pharmacy governmental regulations and public affairs involvement. This would make the course broader and give students a taste of various areas which may help a student decide what particular area they may wish to pursue as a future pharmacist. Regardless of the way the course is designed, the student must take part in at least one project related to the course and its area(s) of interest. Learning by the traditional methods is effective, but actually doing what is being taught is the real lesson.

Although the course would involve extensive planning and money in order to evolve into the diverse program that has been described, the costs cannot begin to outweigh the benefits of exposing pharmacy students to the field of pharmacy which serves as an important part of the foundation of pharmacy—regulations and policies: their forma-

tion, implementation, interpretation and regulation. Previous experience in this area of pharmacy while in school may eventually lead to more involvement once on the professional level. It may be helpful to have a speaker in once or twice a semester to discuss how involvement in regulations and policy is important, but to devise and implement a course will provide a solid support in which students can learn about becoming an active participant in this extremely important aspect of pharmacy. A student could have the opportunity to earn credit that will prove to be very beneficial, not only to the future pharmacist but also to the profession of pharmacy.

The MPhA: A Unique Experience

George D. Garmer, Third Year
Pharmacy Student

After seven years of community pharmacy experience at Freedom Drug in Lansdowne and three summers at Saint Agnes Hospital, I wanted something different when my final PEP rotation came around. I looked through the wild card rotation pamphlet, talked to a few friends, and decided the Maryland Pharmacists Association would offer a wide range of experiences to make for an interesting month.

I found a variety of options upon arrival. Besides an assigned project and a few scheduled meetings, the rotation was somewhat open for discussion with Dave Miller, preceptor and MPhA's executive director. I saw the politics of pharmacy in Annapolis, at The Governor's Prescription Drug Commission Meetings, and at an MPhA board meeting. I touched on the history of pharmacy

when I went through the B. Olive Cole Museum cleaning and organizing the many antiques and pieces of pharmacy memorabilia.

Office management was a major part of the rotation. I helped with mailings, conducted a survey, answered many phone calls regarding a range of topics, gave input on grant proposals and took bids for maintenance work needed in the museum. I saw how important it is to have an effective leader in a business setting to get any work done, and I will surely take this with me after graduation.

I had the opportunity to see pharmacy politics in action this month. On two different occasions I went to Annapolis with Dr. Miller and Dr. Nick Lykos (Chairman of the Legislative Committee). Both gentlemen presented testimony regarding bills in the House of Delegates. The two days were very different. On the first day everything went very smoothly. This was not typical of Annapolis according to Dr. Miller. Our bills were the first to go before the committee and we were back to the Kelly building before 3:30 pm. The second day, two weeks later, was quite different. We went to Annapolis early to have lunch with the MPhA's lobbyist, Robin Shavitz. After lunch we sat in on bill after bill until ours finally



George Garmer, PEP Extern

came up last at 7:00 pm. Dr. Miller said this was much more typical of Annapolis and he was glad I had the opportunity to see it. Overall, they were interesting experiences. They showed me a lot more goes into our law books than the paper and ink needed to print them.

I also attended two meetings of The Governor's Prescription Drug Commission. The commission was formed to evaluate the issue of serialized prescriptions and triplicate prescriptions for controlled medications. The personality clashes were what made these meetings so interesting. I saw some commissioners speak a lot, but accomplish very little. Others said only one thing and it made the meeting, or would bring up an entirely different issue that would be effected by the commissions decisions. When Mr. Miller told me I would be attending these meetings, my original thought was what a bureaucratic waste of time. After attending the meetings, I see how important the bringing together of different professionals is to avert unnecessary laws and regulations which can weigh our profession down that much more.

The MPhA Mid-year Meeting took place during my rotation. Many hours of planning must have gone into the preparation of this meeting for it to have gone as smoothly as it

did. I would recommend it highly to all members and non-members not only as a source of C.E. credits. In addition, it was a relaxing change from everyday pharmacy.

I spent a day with Dr. Richard Baylus, the director of DUR. He explained the process used in evaluating profiles presented by both Blue Cross and Medical Assistance. The program has been shown to be quite successful in identifying prescribing and patient compliance problems. One day certainly was not enough time to see all that DUR does and I would recommend it as a separate rotation.

By far the most interesting part of the month was the opportunity to overhaul the B. Olive Cole Museum. It hasn't had an active curator for about fifteen years. Much work was needed to bring the museum back from the verge of disaster. I started with cleaning all of the artifacts and showcases. Much more work is needed. I am presently researching the various artifacts. I hope to date all of the items and also give some

information about each of them. Also, several boxes of pharmacy bottles were recently donated to the museum by a member of the Association. I cleaned the bottles and organized them in the "Turn of the Century Pharmacy" in the basement of the Kelly Building. I also took bids and will have some of the cabinets in the pharmacy repaired. I often wondered how I could combine my interest in pharmacy and history. The answer lies in becoming the part-time curator of the B. Olive Cole Museum, which was approved by MPhA's Board of Trustees in March. Look for information in the future about the museum in the journal.

An article about my experience at the MPhA would not be complete without saying something about the staff. Their pleasant attitude and helpfulness made the month go by too quickly. I would highly recommend it as a rotation and encourage all students with a lot of pharmacy experience to give the MPhA consideration when they register for rotations.

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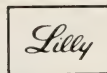


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Sexuality and the Elderly

Geoffrey D. Buff

The issue of sexual activity in elderly people may be summarized as "some do, some don't, and there is nothing wrong with either." Healthy elderly are capable of engaging in sexual activity. Whether they do or not depends primarily on availability of partners, the degree of sexual activity earlier in life, and the interference of medical illness. Normal age-related changes in physiology and psychology have to be distinguished from pathological phenomena.¹

Myths and stereotypes regarding sexuality in old age persist among older adults, their children and at times among the health professionals who work with older adults.^{2,3} These myths center on the theme that the aged are sexless beings and that those with sexual desires are perverted. Belief in these myths and support for the attitude they reinforce ignores the complexity of sexuality and is unfortunate for everyone.²

In aging men and women, many normal physiological changes occur which, with education, reassurance, and appropriate medical treatment need not reduce the pleasure or enjoyment associated with sexual practice. Understanding the sexual adaptations and changes associated with aging may help the health care professional relieve needless distress and dysfunction in these patients.¹

History of Sexuality in the Elderly

Cultural stereotypes greatly impact the experience and treatment of older people and many of the negative attitudes older adults have about their own sexuality are imposed by society.^{3,4} To this day, sexuality is often associated with procreation and sexual feelings in older adults are tabooed by society. However, throughout history, these stereotypes and perceptions have not always been so negative.

During the "Golden Age" of Greece (600-150BC) the average life expectancy was 30 years. The aged were in their forties and fifties and according to historical writings led active sexual lives.⁶

During the Middle Ages (14th Century), the church's conviction was that the sex act was to be avoided except for the purpose of procreation and not to be enjoyed. Despite the efforts of the church, the period was characterized as being sexually open.⁴

Contrary to popular belief, sexual behavior per se was not condemned by the Puritan ideology. In fact, denial of sex within marriage by either spouse was a punishable offense. Judging from historical data, sex in the later years was looked on positively.⁶

The major sexual concern during the Victorian era of the 1800's centered on the dangers of sexual indul-

gence for both men and women. Sex was viewed as physically demanding and too much was dangerous to a man and could be debilitating, especially the elderly.⁶ It is this portion of our society's heritage that has given rise to the myths and misconceptions that the elderly are asexual beings.

Physiological Changes

As the average life span has increased, so has the need for physiological and psychological adaptations, including adaptations in sexuality.³ In addition the requirements of having adequate health and desire, the manner of sexual expression is influenced to a degree by the senses, touch, smell, taste, hearing, and seeing. These functions gradually decline with age along with hormone levels, muscle mass, fat deposits and elasticity of tissues, and they may effect methods of sexual expression.²

Men

Age related changes in the penis consist of fibroelastosis of trabeculae in the corpus spongiosum, and progressive sclerosis of both arteries and veins. The result is erection is often less full in older men than younger ones and takes longer to achieve. Erection also disappears faster in old age and it may take days before another erection after orgasm can be achieved.

In younger men, the prostate gland has well-developed tubuloalveolar glands which contribute significantly to the volume of ejaculate. In men past 60, degeneration occurs leading to the loss of secretory activity by the glandular epithelium. Generally the prostate gland grows larger and its contractions grow weaker. These prostatic changes contribute to the reduction in the volume and viscosity of the seminal fluid with the resulting decrease in the force of ejaculate. Also an increased incidence of carcinoma of the prostate has been correlated with advancing age.^{6,7}

Lowered testosterone levels results in a decrease in the size and firmness of the testes, and the diameter of the testicular tubules that store and carry sperm become increasingly narrowed by layers of non-productive cells. The volume of sperm decreases, and sometimes there is no ejaculate at all, or it seeps out or is ejected retrograde into the bladder. Though no harm occurs with this, some of the pleasure is lost.¹

Women

After menopause, women have sharply decreased levels of circulating estrogen, resulting in physiological changes that affect vaginal tissues and functions.¹ Changes include thinning of vaginal mucosa, shortening of vaginal width and length, decreased volume of vaginal lubrication, and decreased expansive ability of the vagina. This lack of lubrication combined with fragile tissue can lead to pain on intercourse, and eventually

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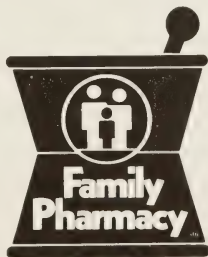
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cause tissue atrophy and infection. Use of topical lubricating creams is helpful, and the treatment of choice. Estrogen therapy is controversial.^{1,2}

The breasts undergo a loss of fatty tissue with the soft, glandular tissues being replaced by fibrous cords eventually leading to decreased size of the breasts. Fatty tissue in the labia majora also shrinks, constricting the opening of the vagina. There is also a decrease in pubic hair. These changes occur rapidly between the ages of 40 and 60.³

Orgasm also changes somewhat in the older woman. Although there is no loss of the ability to experience sexual climax at any age, the number of involuntary contractions decreases by 50%. For some women, orgasm becomes an unpleasant experience when the rhythmic contractions of the uterus become painful spasms.^{1,6}

Older women who abstain from sexual relations for an extended period of time experience greater shrinkage in the size of the vagina, a problem called "disuse atrophy". When these women attempt sexual intercourse they find it painful and unpleasurable. This type of problem is difficult to correct; therefore, it is easier to preserve sexual function than to restore it.³

Changes in Sexual Response

The older man requires a longer time to achieve a full erection. In the aged male, the scrotal vasocongestive response to sexual tension in the excitement phase is markedly reduced, and frequently there is no evidence of this at all. Thickening of the skin and tunica dartos, a layer of smooth muscle, may not occur. This is attributed to the increased relaxation and sagging of scrotal tissue since elasticity of this organ is diminished.⁶

Testicular elevation that occurs in younger males in the late excitement phase is reduced in older males. While younger males can not ejaculate until full testicular elevation has occurred, older males will ejaculate with the testes elevated only slightly. Additionally, the anticipatory feeling of orgasmic inevitability is uncommon in elderly men.⁶ The decline in male sexual activity may be associated with a variety of related factors such as excessive food or alcohol, monotony in the marital relationships, anger, and for those who may still be working, preoccupation with major work-related problems.³

The physiological counterpart of the male erection is vaginal lubrication in women. Therefore, lubrication of the vaginal tissues resulting from stimulation during the excitement phase of sexual response takes longer in older women. Young women lubricate in 10–30 seconds, whereas older women take from one to three minutes. Also there is a reduced amount of lubrication.⁶ Additionally, the post-orgasmic phase is more rapid in that the clitoris retracts and shrinks faster, compared to younger women.¹

Psychosocial Aspects of Sexuality and the Elderly

The physical changes that occur in the body can af-

fect the older adult's sexual self-image. The older adult may feel that his/her physical appearance is unattractive to persons of the opposite sex. These changes in body image may cause stress to those that are beauty conscious.^{2,3} Few changes with age are so threatening to ego, identity and the sense of well being, so suggestive of one's mortality and impending death as those related to appearance.⁷

By the 6th decade of life, many males have found out they are not as successful as they had hoped to be and that their previously held definitions of success are emptier than they had anticipated. In addition, boredom with life patterns and even marital patterns make it easy to perceive how this middle-aged depression could masquerade as "male menopause".⁷

For many women menstruation has been their badge of femininity. As long as it continues, they may still feel that they are young and attractive, despite the changes that they have slowly taken place over the years.⁸ Because of myths and misconceptions, many women still believe that after menopause there will be a considerable decrease in sexual satisfaction, despite evidence to the contrary.⁷

Additionally, for women, marital status appears to be a critical factor for continued sexual involvement because of the fewer number of sexual outlets for the single older female. Lack of a partner may be an especially significant aspect for elderly women. There are 5.3 times as many widows as widowers, and two-thirds of America's older people are female.^{1,2,3}

Effects of Illness and Therapy

With the exception of specific existing diseases, physiologic changes do not ring a mandatory curtain on sexuality in either aging men or aging women. A number of intercurrent illnesses, physical or psychologic, can temporarily lead to a decrease or even disappearance of sexual expression. However, health professionals should be aware that these need be only temporary interruptions rather than causes for permanent cessation of sexual expression in all cases.⁷

Some physical conditions can directly affect genital function. For instance, diabetes can cause organic impotence in men, and women report difficulty in lubrication, although adequate estrogen is present. However, potency can generally be restored when the diabetes is controlled.

Both degenerative and rheumatoid arthritis can impact on the mechanics of sexual intercourse. For these patients, a firmer mattress or simply changing positions may help alleviate some of the physical discomfort.

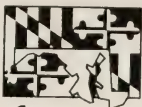
Problems with sexual function in patients with cardiac problems often result from psychologic misconceptions. A major portion of the problem is fear that sex could be dangerous. Generally, however, a patient that is fit enough to walk around the block or climb a flight of stairs is fit enough to resume sex. Death of a heart attack as a result of intercourse is highly unlikely (less than 1% of sudden cardiac deaths).^{1,6}

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Other disorders or conditions that can result in interference of sexuality include stroke, colostomy, breast amputation and prostate problems. Although erectile dysfunction is common after prostate rejection, it is most likely psychologically related. These other conditions take their toll psychologically also, and usually there is no physical reason to abstain from sex.

There are numerous medications that impair erection and delay ejaculation, continued use of which may lead to impotency. Tricyclic antidepressants and antipsychotic medications with their anticholinergic effects impair erection. Antihypertensives, such as guanethidine and reserpine also cause erectile dysfunction.^{1,7}

Implications for the Health Care Professional

Among other resulting behaviors on the part of professionals and society at large, there is the noticeable imposition on older persons of the "sick role". It is only a short path from the stereotype of a sick, dependent, almost frail person to "asexual".⁷ It is important for the health professional to realize that old age is not a disease, and that old people are not all sick. If professionals hold this attitude, they most likely project it onto their patients which may be detrimental to their well being as well as sexuality.

It is important to realize that persons who have been very active in their younger years tend to continue their sexual expression into later life. Data indicate that approximately 80% of aging men continue to be interested in sex and that 1 of 4 men aged 78 or older is still regularly sexually active. And contrary to expectations, these older individuals are not hesitant to discuss sexuality, particularly their own. It is usually the professional who has problems approaching the subject.⁷ Equally important is to note that the elderly are not a homogeneous group and that there are some older people who have never experienced sex and are content.²

Sexuality is a lifelong process that does not disappear as one ages. Persons never cease to be males or females. It is important that the health professional know about all of the physical and psychological changes that occur with aging, and to be able to comfortably consult the elderly with changes that may afflict their sexuality. When discussing sexuality, one should assess the older adult's current feelings and concerns, and the degree of change that is desired.³

In order to ensure continued quality of life, the health professional should take sexual histories along with medical histories.⁷ It is equally important to know an elderly patient's sexual activity as it is to know their medical history or medication history when devising a treatment regimen. When taking a sexual history, it is important that the professional not act shocked by or make light of people's beliefs and attitudes regarding sexuality.

Specifically for pharmacists, there are a number of communication skills which should be mastered and practiced.⁷ These include:

- 1) Being aware of one's own beliefs, values and attitudes toward aging; the aged, and toward sexuality in general.
- 2) Create an atmosphere of mutual trust and respect conducive to discussion of sexual concerns.
- 3) Listen when patients ask questions and look for nonverbal cues of additional concerns.
- 4) Initiate communication and elicit verbalization of underlying concern.
- 5) Keep conversations private and confidential.
- 6) Forewarn patients about possible unwanted side effects.
- 7) Ask patients about their medication treatment including side effects.
- 8) Stay educated as to side effects and uses of prescription and OTC drugs.
- 9) Intervene and contact the physician if a patient expresses concern about therapy.
- 10) Keep in mind that a large proportion of prescriptions are dispensed to the elderly, but that new drugs are not tested in this group. Report any unusual concerns to the FDA.

Summary

Healthy older adults are capable of maintaining a level of sexual activity. People must realize that changes in sexual patterns due to illness need only be temporary. Myths and stereotypes held by the public and health professionals impact on the elderly and their views of sexuality. Throughout history, attitudes have not always been so negative. Health professionals need to know about the physiological and psychological changes that occur with aging. These same professionals must be able to convey their knowledge to their patients and should not be afraid to discuss the topic of sexuality with their patients. Treatment regimens must be developed so as to not impact on the elderly patient's sexuality. The pharmacist in particular must acquire and use certain communication skills in order to communicate with their elderly patients, especially regarding matters dealing with sexuality.

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Full Range of Mutual Fund Benefits often Overlooked

Daniel K. Hays

Over the years, mutual funds have become a popular form of investment for many individuals. In fact, according to the Investment Company Institute, total mutual fund assets reached a record high of \$1.028 trillion in May 1990.

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Then . . . seize the day!

Daniel K. Hays is a financial consultant with Advest, Inc. in Lutherville, Maryland. If you have any questions, he can be reached at 800/272-7368.



DRUG PRODUCT QUALITY Review

A PUBLICATION OF THE USP DRUG PRODUCT
PROBLEM REPORTING PROGRAM

No. 17

AGITATED BY FLUOROURACIL

The USP Drug Product Problem Reporting Program (DPPR) has received nearly 100 reports from pharmacists across the nation involving precipitation or crystallization in various brands of Fluorouracil Injection. Several reporters discovered a white substance on or around the stopper inside a sealed vial.

While some reporters observed "crystalline matter" in the solution, others described the substance as looking like "some type of growth". As directed by the manufacturers' instructions and the USP monograph, reporters often tried unsuccessfully to dissolve the substance with heat or agitation.

...

USP REVIEW

Precipitation is a common occurrence with Fluorouracil, particularly as a result of exposure to low temperatures. However, the ease with which the precipitate dissolves may depend upon the size and location of the precipitated crystals. For example, during the filling process, it is possible for liquid to splash up into the neck of the vial. After the rubber stopper is inserted, crystals may then become lodged between the stopper and the glass. One firm indicates that these crystals may be more difficult to dissolve. That firm has also implemented changes to tighten controls during its mixing process in an effort to reduce the incidence of Fluorouracil precipitation.

The monograph for Fluorouracil Injection is found on pg. 583 of *USP XXII*. The official packaging and storage requirements state that Fluorouracil Injection should be stored at controlled room temperature and that the product should be protected from freezing and exposure to light. The monograph also states that if a precipitate is formed as a result of exposure to low temperatures, it may be redissolved by heating to 60° Celsius with vigorous shaking. It should be allowed to cool to body temperature prior to use.

Because precipitation of Fluorouracil may be a result of exposure to low temperatures, pharmacists may notice a greater incidence of product precipitation during the winter months. This product should not be stored in an area that lacks adequate heating. Due to the inherent toxic nature of Fluorouracil, pharmacists must use caution in the handling of this substance and are urged to heed safety procedures regarding exposure to Fluorouracil.

To report drug product problems or for further information, call the USP DPPR Program at 1-800-638-6725.



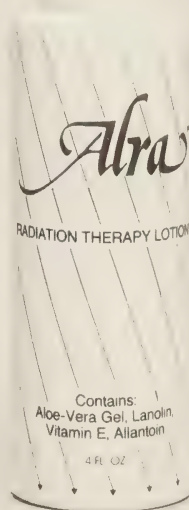
Massengill Feminine Cleansing Wash is a new, extra gentle alternative to soap, specifically made for intimate cleansing. Now nationally available, Massengill Wash is sold in 8 oz bottles.



Carter-Wallace has just introduced the fastest ovulation predictor and pregnancy test kits available. First Response 3-minute Ovulation Predictor Test and First Response 1-minute Pregnancy Test replace the older versions in response to consumer demand and advancing technology.



ICN Pharmaceuticals has announced the availability of Insta-Glucose, a ready-to-use liquid hypoglycemic treatment in a squeezable gel form.



Radiation patients can now obtain quick and effective relief from acute radiation dermatitis with ALRA, an aloe-vera based lotion with lanolin, vitamin E and allantoin. Available in 4 ounce bottles, free trial samples and information can be obtained by calling (516) 741-6360.

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Continuing Education

Continuing Education Quiz

The Maryland Pharmacist JUNE 1991

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by October 31, 1991. A continuing education certificate for one contact credit will be mailed to you within 30 days. Please type or print clearly.

Name _____

Social Security Number _____

Address _____

City/State/Zip _____

Is this program used to meet your mandatory CE? ☐ Yes ☐ No

Did this article achieve its stated objectives? ☐ Yes ☐ No

How long did it take you to complete the program? _____ minutes

Dry, Chapped Lips

1. The primary etiologic factor in promoting lip cancer is:
 - a. accumulated UV irradiation.
 - b. cigarette smoking.
 - c. environmental pollutants.
 - d. neoplasms metastasizing from other cancers.
2. Sunscreens, to the greatest degree, are derivatives of the chemical designated by the initials:
 - a. APAP.
 - b. ASA.
 - c. PABA.
 - d. PVP.
3. Which of the following drugs is most likely to cause dry, irritated lips?
 - a. Achromycin
 - b. Accutane
 - c. Tegretol
 - d. Trilafon
4. The term that best describes serious inflammation of the lips is:
 - a. cheilosis.
 - b. glossitis.
 - c. ichthyosis.
 - d. xeroderma.
5. The type of cells that produce the substance that is the body's "sunscreens" is the:
 - a. granulocytes.
 - b. keratin cells.
 - c. melanocytes.
 - d. sebaceous cells.
6. All of the following OTC ingredients are rated safe and effective for treatment of chapped lips EXCEPT:
 - a. aloe.
 - b. cocoa butter.
 - c. petrolatum.
 - d. shark liver oil.
7. All of the following points of information are appropriate advice on the application of sunscreen lip products with the EXCEPTION of:
 - a. "apply the product 45 to 60 minutes before exposure to the sun."
 - b. "dry your lips thoroughly before applying the product."
 - c. "reapply the product hourly while exposed to the sun."
 - d. "reapply the product freely after swimming or sweating."
8. Which of the following products contains allantoin, padimate O, pyridoxine and titanium dioxide?
 - a. Blistex
 - b. Chapstick
 - c. Herpecin-L
 - d. Lip-Gard
9. All of the following contribute to dry, cracking, chapped lips during the winter EXCEPT:
 - a. low relative humidity.
 - b. whipping, cold air.
 - c. artificially warmed indoor air.
 - d. insufficient sunlight.
10. The ingredient listed below that is a CHEMICAL sunscreen rather than a PHYSICAL sunscreen is:
 - a. padimate.
 - b. red petrolatum.
 - c. titanium dioxide.
 - d. zinc oxide.

Classified

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THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Horn and Horn Smorgasboard on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (301) 358-7036.

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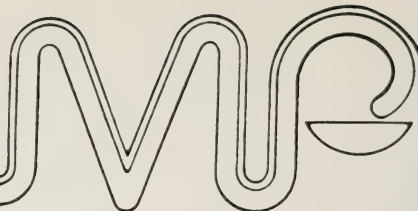
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July, 1991

No. 7



Pharmacy in Williamsburg



JULY, 1991

VOL. 67

NO. 7

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The Maryland Pharmacist (ISSN 0025-4347) is published monthly by the Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201. Annual Subscription—United States and foreign, \$10 a year; single copies, \$1.50. Members of the Maryland Pharmacists Association receive The Maryland Pharmacist each month as part of their annual membership dues. Entered as second class matter at Baltimore, Maryland and additional mailing offices. Postmaster: send address changes to: The Maryland Pharmacist, 650 West Lombard Street, Baltimore, Maryland 21201.

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YOU CAN MAKE A DIFFERENCE!!!

Pharmacy practice is rapidly changing. These changes include new terminology such as "pharmaceutical care" and "cognitive services." We are witnessing changes in pharmaceutical education, reimbursement, and scope of pharmacy practice.

Change is exciting, but it can also be intimidating. How are these changes going to affect ME? How will they affect my patients? What will happen to my business? Will I be capable of meeting the challenges of the 90's?

Let me suggest an action to decrease the anxiety associated with change: DEVELOP THE CHANGE. That is, become involved in the fate of your profession. Pharmacy needs YOUR (yes, YOU!) input. Ask yourself, What can I do to affect change? For example, by serving on an MPhA committee, you can directly affect legislative outcomes, the content of pharmacy practice standards, pharmacy reimbursement, or the role of pharmacy technicians.

It's easy to "develop the change." Just call the MPhA office and volunteer for a committee. Or, call me. Or, call any member of the Board of Trustees. You are important; we want to hear from you. Think of the consequences if you don't call: legislative changes may occur that you don't like; pharmacy practice standards will be adopted that don't fit into your practice; you may lose the opportunity to get reimbursed for special services you offer.

YOUR opinions, YOUR expertise, YOUR talents CAN make a difference. Please share them with your fellow MPhA members. And remember, YOU CAN MAKE A DIFFERENCE.

Ilene Zuckerman, Pharm.D.

MPhA President

Editors Note: This month's issue of *The Maryland Pharmacist* features the historical apothecary in Williamsburg, Virginia. It's a perfect weekend getaway for the summer!

Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Correspondence Course

Counseling Patients on Parkinson's Disease

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, OH

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, OH

Goals

The goals of this lesson are to:

1. explain the physiologic and biochemical considerations involved in Parkinson's disease;
2. discuss current therapy for treating this disorder; and
3. summarize important information to convey to patients about their medications and disease.

A professional development
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Gossel



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Objectives

At the conclusion of this lesson, successful participants should be able to:

1. demonstrate knowledge of the usual signs and symptoms of the disorder;
2. choose from a list, drugs used to treat Parkinson's disease; their mechanisms of action, adverse reactions, precautions and warnings, and factors that influence activity;
3. exhibit an understanding of why multiple drug therapy is warranted for some persons; and
4. choose from a list, important points to convey to persons receiving a prescription drug for treatment of Parkinson's disease.

Over 400,000 Americans have Parkinson's disease. Parkinson's disease is a progressive neurodegenerative disorder that has well established clinical and pathological features. Dr. James Parkinson (1817) first described it as "the shaking palsy." Charcot in the late 1800s, referred to it as "Parkinson's Disease."

Signs and Symptoms

Parkinson's disease normally develops insidiously, generally beginning between ages 45 and 65. It may appear earlier, but less than 10 percent of patients display symptoms before age 50. Males and females are equally affected.

Clinical hallmarks include: tremor, rigidity, bradykinesia (slowed move-

ment), and gait and postural abnormalities. Symptoms are often relieved when the patient is at rest.

Tremor is the initial symptom in 60 to 70 percent of patients, and approximately 90 percent of all sufferers experience this at some point during the disease. The hands are most commonly affected, with the legs, jaw and tongue also involved. Unilateral at first, tremor usually becomes bilateral with time. The hand becomes flexed, with the distal joints in extension. Tremor in the fingers give the patient an appearance of rolling a pill between the thumb and index finger. This results in the designation "pill rolling tremor." While embarrassing, the tremor is not disabling. It may worsen during periods of stress or emotion.

Rigidity accompanies muscle aches and stiffness. It is frequently seen in the neck and back, and may be accompanied by occipital (back of head) headache. The term "cogwheel rigidity" describes a diagnostic characteristic of passive movement of the involved rigid extremity which appears to have a "ratchet" quality.

Bradykinesia may be reported early in the disease as a slowing or lessening of ability to undertake normal (automatic) activities such as eating, dressing and bathing. Manual dexterity is reduced, making common movements extremely difficult. Movement loss includes lack of swinging the arms when walking, decreased frequency of swallowing which results in accumulation of saliva in the mouth with drooling, reduced blinking frequency, and a fixed facial expression which is called a "masked face." The patient's body appears flexed at the head, trunk, and extremities. This causes a stooped posture with head bent forward, legs flexed at the knees and arms bent at the elbows resulting in poor balance. A slight or sudden unexpected movement can result in falling. Multiple contusions and fractures are common.

Table 1**Signs and Symptoms of Parkinson's Disease**

Micrographia (small handwriting)
Hypophonia (weak voice)
Dysarthria (articulation disturbance)
Constipation
Edema of the feet
Seborrhea of scalp and forehead
Autonomic dysfunction
Orthostatic hypotension
Urinary incontinence
Impotence
Sensory symptoms (numbness, coldness, burning, akathisia, pain)
Hearing impairment
Dystonia
Psychiatric abnormalities
Dementia and depression
Speech (monotonic, slow)
Presence of Lewy bodies

Because of the flexure of the body and loss of automatic functions, including natural swinging of the arms, walking becomes difficult. Often the patient increases his pace to prevent falling or losing balance. The Parkinson patient has trouble coordinating his feet in concert with the rest of his body, and this gives him a "start hesitation" or appearance of frozen motion. These, and other signs and symptoms, are outlined in Table 1.

An accurate prognosis of parkinsonism is often difficult. Many patients deteriorate slowly, while others show dramatic decline in physical and mental activity in a relatively short period of time.

Etiology

The exact cause of Parkinson's disease is unknown. There is insufficient evidence to positively link blood types, cancer, coronary heart disease, cerebral atherosclerosis, viral infections, vaccinations, exposure to drugs, fumes, gases or radioactive materials, alcohol consumption, or animal contact with the disease. Heredity is generally dismissed as a contributing factor, although this has not been totally ruled out. About 50 years ago, one-half or more of all patients were victims of encephalitis acquired from an early bout of epidemic influenza.

It has been proposed that premature aging of central dopaminergic neurons is the cause. Research confirms that cells within the substantia nigra area of the brain decrease in number with aging, as do dopamine receptors and dopamine synthesizing enzymes. On the other hand, if the etiology were as simple as the theory proposes, then most or all people who reach advanced age would develop symptoms of Parkinson's disease. Although aging is a risk factor, it is not the etiologic cause.

There is intensive research underway to identify an environmental toxin cause. At this point, the strongest statement on etiologic causes is that Parkinson's disease is multifactorial in origin and *might* result from a combination of numerous environmental toxins in persons genetically predisposed.

"Parkinson-Like" Syndrome. Any drug that depletes dopamine can cause extrapyramidal symptoms, commonly referred to as Parkinson-like symptoms. These include reserpine, haloperidol, metoclopramide, and some phenothiazine derivatives. It is not uncommon for patients taking large doses of phenothiazines to require concomitant therapy with antidyskinetics such as benzotropine (Cogentin) or trihexyphenidyl (Artane) to attenuate drug-induced Parkinson-like symptoms.

The Action of Dopamine. Dopamine is a neurotransmitter that controls physiologic functions centrally, and peripherally in the vascular system, kidney, and GI tract. Neurons stimulated by dopamine are "dopaminergic." There are two known types of receptors: D-1 and D-2. D-2 activity is most closely related to clinical response in Parkinson's disease. In the brain, dopamine and acetylcholine produce opposing effects — one stimulates activity and the other decreases activity. Together, they counter each other to control motor movements. Parkinsonism results from either insufficient dopamine, or excessive acetylcholine in the brainstem. Therefore, treatment is aimed at increasing dopaminergic activity or decreasing cholinergic transmission.

Monoamine Oxidase. There are at least two forms of monoamine oxidase (MAO) enzyme in humans. These are termed MAO-A and MAO-B. MAO-A is distributed to greatest extent periph-

erally in the gastrointestinal lining. MAO-B is found in large degree within the brain, but neither is restricted to peripheral or central sites *per se*. Human platelets are a rich source of MAO-B. Strong evidence suggests that platelet enzyme levels reflect the concentration of MAO-B in the brain. This should allow future research to be better focused.

Therapy of Parkinson's Disease

Therapy of Parkinson's disease involves numerous facets. These include drugs, controlled exercise, and much support and encouragement. There is no cure. At most, treatment offers symptomatic relief.

Currently available drugs to treat Parkinson's disease will benefit most patients as opposed to non-drug therapy. With introduction of selegiline (Eldepryl), it may now be possible to halt the progression of the disease.

Table 2 presents an overview of currently used drugs listing major pros and cons for each agent. Most patients require multiple drug therapy to achieve optimal symptomatic relief.

Levodopa. Prior to the availability of levodopa, approximately 30 percent of all Parkinson patients were disabled or dead within five years of onset of disease. By 10 years, mortality and morbidity increased to over 60 percent. Mortality rate overall was three times that of the normal population. Levodopa resulted in drastic delaying of disability and reduced mortality. There was initial hope that the drug would actually halt disease progression, but this did not happen. Today we know that, while levodopa significantly improves life expectancy and quality for the first 5 to 6 years of treatment, after about 10 to 12 years of chronic therapy, benefit decreases and may be lost in many people.

Levodopa is a metabolic precursor to dopamine. Dopamine is not absorbed across the blood-brain barrier. Therefore, it is not possible to treat parkinsonism by administering dopamine. Levodopa readily crosses from the peripheral circulation into the central nervous system. Within the brain, levodopa is decarboxylated into dopamine. Decarboxylation also occurs peripherally, leading to unpleasant adverse effects including nausea, vomiting, and diarrhea. For this reason, the

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decarboxylase inhibitor carbidopa (i.e., Sinemet) is given concurrently to block the reaction. This results in higher brain levels of dopamine, and reduced peripheral dopaminergic activity. Today, therapy with levodopa alone is rarely initiated in newly diagnosed patients.

Levodopa is most active during the first five years of therapy. As the disease progresses and drug therapy continues, each dose produces correspondingly decreased activity. This is referred to as the "wearing off" effect. Some patients also experience fluctuations in activity that are unpredictable and erratic, referred to as the "on-off" phenomenon. Additionally, abnormal involuntary movements (dyskinesia) increase. Selegiline, pergolide, and bromocriptine find their greatest use in treating these drug failures.

Many specialists advise that levodopa/carbidopa should be the initial therapy of Parkinson's disease, and that it be given as long as possible to control the disease. Others recommend that drug therapy with levodopa/carbidopa be withheld until the dis-

ease reaches its severe form. The idea is that benefit from levodopa/carbidopa is limited.

Even with all the benefits, combination levodopa/carbidopa therapy still results in a number of adverse effects. These may be due to a combination of pharmacodynamic and pharmacokinetic factors.

Diet can significantly alter levodopa efficacy. For optimal effect, levodopa must be taken on an empty stomach or with a light snack. Amino acids in food compete with the drug for active transport into the blood. They may also change gastric pH or gastric emptying time, and there is evidence they compete with levodopa for entry across the blood-brain barrier. Patients ideally should eat small meals no sooner than 20 to 30 minutes after dosing. This ensures sufficient time for drug absorption, maximizes the chance that the stomach will be empty by the time the next dose is administered, and reduces the amount of competitive amino acids.

Bromocriptine. Bromocriptine (Parlodel) is a potent, long-acting D-2 dopaminergic drug. It is a useful ad-

junct to levodopa therapy, especially in persons with declining drug efficacy, and those who experience random fluctuations in levodopa activity. Adding bromocriptine is one means to reduce total levodopa dosage, and thereby reduce the incidence of adverse reactions.

Bromocriptine is used in some persons as sole drug therapy. It is generally believed that bromocriptine alone will not bring about the same activity as levodopa alone. Because it may induce fewer abnormal involuntary movements, and has a longer duration of action, it may be the drug of choice for responding patients.

Bromocriptine may induce dyskinesia but the outcome is generally mild and continuous, unlike the dramatic on-off pattern with levodopa. In many patients, when bromocriptine is added to levodopa therapy, fluctuations in the short duration response to levodopa disappear because the dosage of levodopa is oftentimes reduced.

Pergolide. Pergolide (Permax) is a mixed D-1/D-2 agonist. It is especially beneficial during later stages in Parkinson's disease when levodopa response is deteriorating. Also, it is useful when clinical fluctuations become uncontrollable.

Pergolide does have its own variety of adverse effects including dyskinesia and symptomatic postural hypotension. Most can be modified by decreasing the dose, or by giving a dopamine antagonist such as metoclopramide (Reglan).

Antidyskinetic Agents. These are mildly to moderately effective in selected patients. Drugs include trihexyphenidyl (Artane), benzotropine mesylate (Cogentin), biperiden (Akineton), procyclidine (Kemadrin), and diphenhydramine (Benadryl). Antidyskinetics were popular prior to introduction of levodopa, mainly because they were all that was available. They are still useful in some patients, especially those with tremor, although levodopa and newer drugs have largely supplanted their use. They may have an additional therapeutic effect when combined with levodopa or other therapy. Antidyskinetics are the treatment of choice for drug-induced parkinson syndrome.

Antidyskinetic drugs are anticholinergic agents that block muscarinic receptor sensitivity to acetylcholine. Some drugs, including benztropine,

Table 2

Important Features of Antiparkinson Therapy

Therapeutic agent	Advantages	Disadvantages
Antidyskinetics (Anticholinergics)	Effective for tremor, dystonia, and rigidity. Long-term side effects.	Limited effectiveness for bradykinesia and imbalance.
Amantadine	Effective for parkinsonian symptoms. Useful in combination with other drugs.	Often has limited period of efficacy. Frequent, dose-related side effects.
Levodopa	Can reverse cardinal parkinsonian features. Sustained effectiveness common. Possible improvement in memory and mood.	Frequent development of dyskinesia and on-off symptoms with chronic use.
Levodopa/Carbidopa	Same as for levodopa alone, with fewer peripherally mediated side effects. Longer duration of dose-by-dose effects.	Increased cost compared to levodopa alone. Possible increased incidence of dyskinesia and on-off symptoms when compared to levodopa alone.
Bromocriptine and Pergolide	Primary and added benefit for all parkinsonian symptoms. Longer duration of dose-by-dose effect than levodopa. Lack of on-off effects and dyskinesias with chronic monotherapy.	Less effective as monotherapy than levodopa. Expensive in optimal dose for some patients.
Selegiline	Extends dose-by-dose effects of levodopa. Might retard progression of Parkinson's disease.	Enhances dose-related levodopa side effects.

also increase dopamine levels within the striatum by blocking synaptic dopamine reabsorption. Antidyskinetic drugs block parasympathetic transmission peripherally, and this is a cause of annoying side effects such as dry mouth, blurred vision, urinary retention, and constipation. Antihistamines also share many of these activities.

Amantadine. Amantadine (Symmetrel) exerts antiparkinson activity by increasing dopamine release in the brain. It also possesses antidyskinetic activity.

Amantadine is not metabolized, but excreted intact in urine. Persons with renal dysfunction may require lower dosage. Extreme caution must be observed when it is used concurrently with antidyskinetics because of additive adverse effects on mental function. Outcome of therapy is often temporary, and described as mildly to moderately effective.

Selegiline. Selegiline (Eldepryl) appears to be one of the most promising new drugs for treatment of Parkinson's disease. It is known as deprenyl elsewhere in the world, and may be prescribed by this name because much of the literature refers to it as such. Selegiline inhibits MAO-B. At doses higher than 5 mg b.i.d., selegiline loses its selectivity and will inhibit MAO-A as well. The implication of this is that the drug may then expose the patient to the same interactions as Parnate and other classic MAO inhibitors.

The mechanism of action has been referred to as "suicide inhibition." This pharmacologic designation refers to a chemically reactive group which is selectively activated by the target enzyme. It then converts to a highly reactive chemical intermediate that irreversibly binds to and inhibits the enzyme. Consequently, "suicide inhibitors" are not active *per se* until they are acted upon by a specific target enzyme. For selegiline, the drug binds reversibly at the active site on MAO. Through a catalytic mechanism, the drug is then converted to its reactive form, which then permanently binds to the active site on the enzyme. At this point, the enzyme is irreversibly inhibited. Only subsequent synthesis of new enzyme can replace it. In studies involving platelets, MAO-A activity is still absent 24 hours after stopping the drug and does not appear to return completely until 2 to 3 weeks later.

Alone, selegiline has little direct

antiparkinson effect in most people, although some will benefit from sole selegiline therapy. It is often described as a valuable drug for causing a "smoother," more sustained response from each dose of levodopa. In some patients, administration of selegiline early in the disease can delay the need for levodopa therapy for several years and extend its usefulness.

Approximately 70 percent of a dose is rapidly absorbed, and peak plasma concentration occurs 30 to 120 minutes following administration. It is converted into three metabolites: amphetamine, methamphetamine, and N-desmethyleselegiline. This suggests that selegiline may be addicting. Addiction potential is unlikely since the amphetamine metabolite is the levo-isomer. This has activity of one-quarter or less than that of dextroamphetamine, and no problems have been seen in years of clinical trials and world-wide use. Selegiline and metabolites are excreted primarily through the kidney, along with some fecal excretion.

The most commonly reported adverse effects are similar to levodopa. They should be expected since its action is to inhibit MAO-B, allowing for increased dopaminergic activity.

Unlike inhibitors of MAO-A, foods that contain tyramine or other pressor amines (e.g., aged foods and beverages) do not induce a hypertensive response with usual therapeutic doses. Patients must be convinced to take the prescribed 10 mg/day dose, and not experiment with more. Higher doses of selegiline may have some inhibitory activity on MAO-A.

Other Therapy

Tocopherol (vitamin E) is under study because of the postulated causative role of environmental neurotoxins with possible oxidative mechanisms within dopaminergic cells that, in turn, cause cellular death. The hypothesis states that interfering with oxidative mechanisms will slow disease onset. A clinical study is currently underway to test this hypothesis.

One departure from pharmacologic intervention is to implant **tissue transplants** of adrenal medulla or fetal cells into the nigrostriatum or caudate nucleus of the affected patient. There are numerous questions, and certainly controversies, about this procedure. To illustrate, the adrenal

medulla may not be the correct tissue to transplant. The source of fetal cells is of concern. The role of immunosuppression therapy and at what point tissue transplants be undertaken are in question. Whether tissue transplantation should be tried, instead of antiparkinson drugs, is controversial. There is little evidence to support tissue transplant therapy at this time. Most patients have not experienced significant improvement.

Patient Information

April is designated as Parkinson's Disease Awareness Month. This affords pharmacists numerous opportunities to answer questions from persons suffering from the disorder, or others who are interested in it. But counseling on Parkinson's disease does not need to be restricted to the month of April — it's important year-around.

The importance of careful adherence to medication and exercise schedules cannot be overemphasized. Drug therapy does relieve symptoms and prolong onset of serious stages of the disease.

Exercise is essential to maintain muscle tone and strength, and to bolster self-esteem. Regular exercise should be as much a part of a Parkinson disease patient's daily routine, as are medication regimens.

Psychological support is extremely important since many patients will get progressively worse, even with therapy. Also, it may depress them to see other patients with advanced Parkinsonism.

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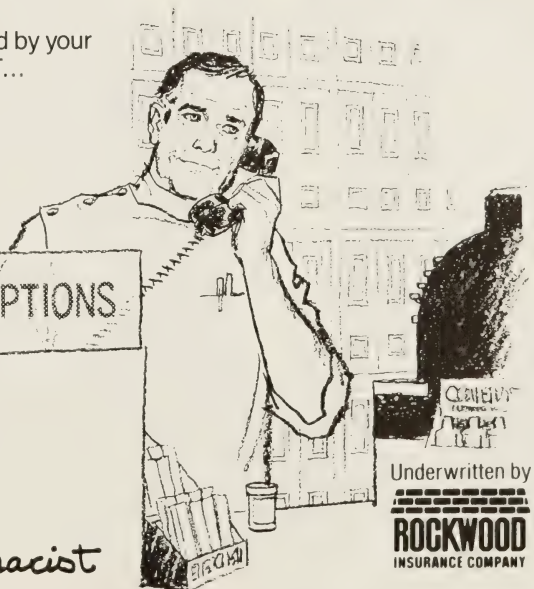
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The Apothecary Trade in 18th-century Williamsburg

The city of Williamsburg boasted a substantial number of medical arts practitioners during the city's 80-year term as the capital of 18th-century colonial Virginia. During the prosperity the city enjoyed as the capital of Great Britain's largest and richest colony in the New World, royal governor William Gooch wrote in 1735 that the town "abounded with physicians."

The number of practitioners apparently fostered an extremely competitive business climate. In the scramble for customers, practitioners sometimes used methods that were somewhat suspect.

George Gilmer, "Chirurgen-Apothecary of the City of Williamsburg," was plagued with a rumor in 1737 that he was dead and had left unpaid debts. At the time, he strongly indicated his rivals were responsible for the "scandalous and groundless" reports. The rumors may have been the product of Thomas Goodwin, a local "Chymist," suffering from the problems of slow business.

Chemists and druggists, who usually sold medicine and drugs but did not engage in medical practice, began to appear in Colonial America after 1725. Since Goodwin styled himself a "Chymist," he probably did not practice medicine and found it difficult to compete with apothecaries who built large practices prescribing and dispensing their own medications. However, the druggists' low prices must have been great annoyances to the apothecaries.

After nine years in his established apothecary shop, Dr. William

Pasteur complained in 1768 that it was hardly worthwhile to import medications for resale at marginal profit "on account of our confounded druggist here."

Dr. George Gilmer, educated in medicine at the University of Edinburgh, established his practice in Williamsburg in 1731 became a respected member of the community and was elected to several civil positions. Gilmer operated one of the most successful practice in Williamsburg. He was able to send his son to Europe to study medicine, and he furnished financial aid to his former apprentice, William Pasteur, for study in London. In addition, Gilmer purchased a half-interest in the Raleigh Tavern in 1752.

Other Williamsburg apothecaries enjoyed success and respected position in the community. Dr. Peter Hay, described as one of the city's "most eminent physicians," operated an apothecary shop on Market Square from 1744 until his death in 1766.

Some apothecaries found the profusion of practitioners in the city created keen competition, and left in favor of a country practice. Dr. George Gilmer, Jr. moved his "practice of Medicine and art of Midwifery," to Charlottesville after several years in Williamsburg.

Dr. John Minson Galt, probably one of the most highly educated apothecaries in 18th-century Williamsburg, established his practice in 1768, after study of the "theory and practice of physick," midwifery, surgery and anatomy in England.

In 1775, Dr. Galt formed a part-

nership with Dr. William Pasteur, Gilmer's former apprentice, and published the following announcement:

"The Subscribers beg leave to acquaint the Publick in general . . . that they intend practicing Physick and Surgery to their fullest extent; and that they intend also . . . to keep full and complete Assortments of Drugs and Medicines, which they will endeavour to procure the very best in Quality, and will take to have fresh by making several Importations in the Year. It is proposed that John M. Galt shall pay his particular Attention to Surgery . . . but will be advised and assisted by W. Pasteur in all Difficult Cases."

The firm was dissolved in 1778.

During the Revolutionary War, Dr. Galt served as a military surgeon as well as director the state apothecary shop at Williamsburg. After the Revolution, Dr. Galt entered into another partnership with Dr. Philip Barraud until Barraud moved his practice to Norfolk in 1799.

Few Williamsburg medical practitioners possessed the formal education of Dr. Galt. Most received their training as apprentices to established medical men and some acquired an additional year or two of additional instruction in England, usually London.

In 1778 at the age of eighteen, Frederick Bryan was apprenticed for four years to Dr. Galt to learn the "Art and Mystery of an Apothecary."

After completion of his training, a beginning medical practitioner

usually opened his own apothecary shop or formed a partnership with an established medical practice.

Williamsburg apothecaries advertised patent medicines and published long testimonials of remarkable cures attributed to them. During the last half of the 18th century, Williamsburg apothecaries compounded and packaged at least two English patent medicines, and printed catalogs of drugs and medicines were available from wholesale druggists in England. Apothecaries generally imported large quantities of drugs and medicines several times a year, and although most medicines were imported from England, some local medicinal plants were employed in the therapeutics of Williamsburg apothecaries. Dr. George Gilmer complained that it was not safe for practitioners to make experiments with native plants, but Gilmer did prepare an ointment from leaves and twigs of pokeberry plants and mentioned several uses for rattlesnake root.

Besides medicines and pharmaceutical equipment, the apothecary usually possessed surgical instruments used for amputation, trepanning, lithotomy, cupping, couching, dissecting, dentistry, and midwifery.

Even though there was a plentiful supply of physicians in 18th-century Williamsburg, no more than five apothecary shops, usually only three, operated at any one time. For a town of approximately 2,000 people that served as the center of the drug trade in Colonial Virginia, three apothecary shops do not seem too many. Some Williamsburg practitioners did not engage in the business of pharmacy. As early as 1736, the preparation of prescriptions by apothecaries for physicians was a common practice in Virginia. After the removal of the state capital to Richmond in 1780, business in Williamsburg declined. Some apothecaries followed the government to Richmond and some moved to other places.

18th Century Medical Materials

Alum (Potassium Aluminum Sulfate or Ammonium Aluminum Sulfate)
—used as a styptic
Cabbage Leaf (*Brassica oleracea*)
—used against scurvy
Camphor (*Cinnamomum camphora*)
—used externally on inflammations such as rheumatism
Chalk (Calcium Carbonate)
—used to treat heartburn
Chocolate (*Theobroma cacao*)
—used in consumptive disorders
Clove (*Eugenia caryophyllus*)
—used to relieve toothache
Cream of Tartar (Potassium Bitartrate)

—a gentle laxative
Foxglove Leaf (*Digitalis purpurea*)
—used for symptoms of heart disease
Garlic Root (*Zingiber officinale*)
—used to calm the stomach
Nutmeg (*Myristica fragrans*)
—used against diarrhea
Peruvian Bark (*Cinchona succirubra*)
—used against malarial fever
Sassafras Bark (*Sassafras albidum*)
—used to purify and sweeten the blood
Tobacco Leaf (*Nicotiana tabacum*)
—used externally to destroy insects such as lice
Willow Bark (*Salix fragilis*)
—used to reduce fevers
Wine (Claret, Madeira, Port)
—used in fevers of the typhous kind



The Pasteur & Galt Apothecary

The word "apothecary" is the Anglicization of a Latin word which, in ancient Rome, was used to designate a storage room for wine and other necessities. Later in the Latin period, the word "Apothecarius" evolved to designate the person in charge of the storage room. It was in Germany in the Middle Ages that the word apothecary was first applied to pharmacy. In the 18th c. the word apothecary was used when referring to both a medical professional and his shop. The word pharmacy, from Greek meaning remedy, is today used in the United States to designate the place where medicines are sold.

Building—This is a reconstructed building that was built on the site of an original apothecary. The front of the building is covered with wood cut into blocks to resemble stone. This technique is called rustication. Rustication was an architectural fad in areas where building stone was hard to come by. At Mount Vernon one side of George Washington's home and a few of the out buildings are covered in this manner.

Sign—The mortar and pestle has for centuries been the symbol of pharmacy. The single snake entwined around a staff is the symbol for Aesculapius, the Greco-Roman god of healing. This is not the Caduceus, the modern symbol of the physician which consists of two serpents entwined around a staff with a pair of wings at the top. The inscription on the sign, "Major agit deus" means "God does the greater part."

Training—In the English tradition the doctor studied at a medical school, earned a degree, and operated like a modern internist. The apothecary, trained by apprenticeship, prepared and sold medication

but was also allowed by law to examine, diagnose, and prescribe. The surgeon also trained by apprenticeship and performed all forms of external treatment and work using the hands or instruments. Most colonial doctors ran their own apothecaries and often performed surgical work. Many colonial doctors trained by apprenticeship within the colonies. Some colonial doctors had formal degrees from European universities, but this was not common. Upon completing their apprenticeship, a few doctors continued their education in Europe through private study and/or practical hospital experience. The first medical school in the colonies opened in 1765 in Philadelphia.

Dr. William Pasteur (ca. 1737–1791) was the son of Jean Pasteur who came from Switzerland in 1700 and practiced as a barber and wigmaker in Williamsburg. Pasteur apprenticed under Dr. George Gilmer, a Williamsburg physician who had been educated at the University of Edinburgh. In addition, Pasteur studied at St. Thomas's Hospital in London. Upon returning to Williamsburg, he opened an apothecary in 1759. He married Elizabeth Stith, daughter of the Reverend William Stith, President of the College of William & Mary. He became Mayor of Williamsburg in 1775 and it was during his term of office that Lord Dunmore removed the powder from the Magazine. Dr. Pasteur also served as an alderman and on the Court of Directors for the Public Hospital.

Dr. John Minson Galt (1744–1808) was the son of Samuel Galt, a goldsmith, who emigrated from Ayrshire, Scotland in the 1730s. Galt attended the College of William & Mary and began his medical education as an apprentice in Williams-

burg. Though the documentation is circumstantial, it is very likely that he apprenticed under Pasteur. He completed his education in London studying at St. Thomas's Hospital, under Hugh Smith and Colin MacKenzie receiving certificates in anatomy and surgery, midwifery, and general physick respectively. He returned to Williamsburg and began the practice of medicine in 1769. He married Judith Craig, daughter of Alexander Craig, a saddler of Williamsburg. Dr. Galt was a vestryman at Bruton Parish Church, a member of the local Masonic Lodge, a member of the Committee of Safety, a member of the Board of Directors of the College of William & Mary, a surgeon in the Revolutionary War, a member of the Court of Directors for the Public Hospital, and later a visiting physician to the Hospital. His son, Alexander Dickie Galt, also became a doctor and was associated with and successor to his father's practice.

In 1775 Dr. Pasteur and Dr. Galt announced their partnership in the *Virginia Gazette*. This partnership was to last for three years. The Pasteur & Galt Apothecary represents the time of this partnership; however, the interpretation illustrates the entire 18th century.

All of the items behind glass, the delftware and dark glass bottles in the front room, and the furnishings and equipment in the back room are original, but not necessarily to the Shop. From Dr. Galt's own collection are the marble pill tile in the front window, the large marble mortar dated 1 May 1774, and the desk in the back room. Some of the items behind the first section of glass doors, such as the wooden pill boxes and the glass jars with metal lids, along with the amputation in-

struments in the back room are early 19th century.

The blue and white jars on the west and north walls are English delftware. The tobacco jars in the lower left corner along the west wall are Dutch pieces. Delftware acquired its name from the Delft region of Holland where this type of pottery was popularly produced. A more descriptive name for this type of ceramic is tin enamel ware or tin oxide glaze ware. It actually originated in the Near East and entered Spain during the Islamic conquest, eventually spreading all over Europe. Production of delftware in England began in the middle of the 16th century.

The large, dark glass bottles are English as well. Most of them are of a deep purplish-blue hue known as black amethyst. The bottles designated by symbols are dark green. These symbols are old alchemy symbols representing, from left to

right, the metals iron, copper, gold, and mercury. All other medical labeling is in 18th century Latin abbreviation.

Theory—The theory of disease was based on physics. There was limited knowledge of chemistry and biology. An illness was thought to be caused by some kind of physical change or imbalance of the solids and/or fluids (humours) that composed the body. The term "humour" refers to *all* of the fluids of the body. Treatment was a combination of medication, diet, proper rest or exercise, and blood letting. These treatments were administered in various combinations to either fix, change, or counteract the patient's physical symptoms. The old Galenic theory of disease based on the four humours was being replaced during the 17th century due to technological advancements in professional medicine.

Pharmacy—The doctor im-

ported most of his pharmaceutical ingredients including botanicals, minerals, and animal products. Ready-made and patent medicines were also imported and available for sale by various retailers. These medications took on various forms. Most common among forms were liquids such as tinctures and spirits (alcohol based), syrups (sugar and water based), and decoctions and infusions (water based). Electuaries and conserves resemble sugar pastes. Other forms included ointments, lozenges, powders and pills.

Pills (Latin for ball) were infrequently prepared in the 18th century; however, when they were prepared traditionally it was by hand. A mass was created by combining powdered dry and moist ingredients. This was rolled into a length called a pill pipe. The pipe was cut into approximately equal sections and rolled between the fingers into balls. The pill machine on the back



counter was developed in the 18th century in Germany and was introduced into this country around 1800. The pill machine helped speed up manufacturing and improve uniformity of the pills. Once prepared, medications would be stored above in the jars and bottles; whereas, raw materials were kept in the drawers below. Some examples of medications include: syrup of ginger or troches (lozenges) of chalk to treat digestive discomforts. We still drink ginger ale and use Tums made of chalk for the same purposes. More important to Virginians was the use of Tincture of Peruvian Bark for treating ague or intermittent fever which was malaria. Isolated from the Peruvian bark in 1820 was the active ingredient—quinine—still a viable treatment. Not all medicines will be successful, for example, Icteric Pills made with soap and used for jaundice did not work.

Blood-letting—Bloodletting was done to reduce inflammation and inflammatory fevers. The most common tool for bleeding was the lancet, a small single-blade knife that comes to a point. The lancet could be used almost anywhere, anytime, and by anyone to remove any amount of blood. In most cases the lancet was used to puncture a vein, this technique was called venesection. Another technique, called scarification, entailed making several small punctures in a capillary bed. In the early 18th century a multi-blade, spring-loaded mechanism, a scarificator, was developed to replace the lancet in this technique. In combination with scarification, cupping glasses were often employed. By burning a piece of lint or tow within the cup the oxygen was removed creating a vacuum. This vacuum cup was placed over the scarified area to draw the blood. This was known as wet or gorey cupping. Another form of cupping is dry cupping. The vacuum cup was placed over unbroken skin, thus breaking blood vessels with the suction in order to draw blood to the surface of the skin. Another tool for bleeding was the leech. Most com-

monly used on children whose small veins could be damaged by the lancet, the leech was also used on everyone to remove blood from areas considered too delicate to cut (around the face), hard to reach with the lancet (on the gums), or from the localized inflammation of bruising (around broken bones and black eyes). Leeches are presently being used in reconstructive micro-surgery such as the reattachment of fingers and ears, skin grafting, and experimentally in the treatment of glaucoma.

Surgery—The word "surgery" literally means "handwork," therefore it included all forms of external and manual treatment. In a private, domestic practice surgery was performed in the home. The first medical hospital to appear in the colonies was opened in Philadelphia in 1751; hospitals of this kind did not exist in Virginia. A Public Hospital for the mentally insane was established in Williamsburg in 1773. During the Revolution, two military hospitals were set up, one at the Wren Building on the college campus and the other at the Governor's Palace.

Among the more common surgical procedures were dental extraction, setting broken bones, amputation, and lithotomy. Surgery was limited because of the lack of anesthesia and the lack of antiseptics. There was no way to control pain, and there was no effective way to prevent infection once it occurred.

Dentistry—Cleaning the teeth was a cosmetic concern of the time. Individuals would find recommended receipts for abrasive mixtures in books on medicine and beauty, or they could create their own mixtures. These abrasive materials consisted of such things as pumice, cream of tartar, baking soda, salt, cinnamon, and an ingredient called dragon's blood which was a dried plant resin of an orange color. These abrasives were applied, either dry or with such liquids as vinegar or water by rubbing the material on the teeth with the fingers, a rag or a stick, such as a liquorice root with a

frayed end. By the late 18th century, the first modern-looking toothbrush was invented and was made of cow's hairs tied to an ox bone handle. Drs. Pasteur & Galt advertised the selling of toothbrushes, but the exact structure of them is unknown.

Topical, temporary relief of toothache pain, according to Dr. Laurence Heister (1743), could be obtained by applying Caryophyllus Aromaticus or clove to the affected part. Clove oil contains Eugenol, an active ingredient still used in dental preparations today.

Dental extractions were often the result of severe pain due to normal tooth decay from the lack of improper care. The one dental instrument displayed in the Apothecary Shop was called a "toothkey" or "turnkey" and was for the specific purpose of removing lower molars. Other instruments were used for removing teeth in other areas of the mouth. It was also possible to fill cavities, transplant teeth from one mouth to another, to apply braces, and create dentures.

Typically, the doctor-surgeon would pull teeth; however, Williamsburg had a dental specialist for two years, Dr. John Baker, who arrived in town in 1772. There are records of blacksmiths and silversmiths in Europe and in the northern colonies who occasionally pulled teeth, but there is no evidence of this occurring in Williamsburg.

Fractures—Simple and some compound fractures were commonly set, bandaged, and splinted. A variety of splints and immobilization equipment were available; however, we only show a small sample of devices here: there are two lower leg splints and a fracture box (for elevating and immobilizing the leg when it is uncomfortable for the patient to lie on the side, the common position), a knee splint and an arm sling. Recuperation time for a fractured leg was up to 8 weeks and for a fractured arm, 6 weeks.

Amputation—A severe compound fracture, shattered bones, extensive wounds, and diseases of the flesh and bones were all grounds for

amputation. If the operation was to be performed on the lower body, the patient would be laying on a table; if the upper extremities were the focus, the patient would typically be sitting up in a chair. At least four assistants were necessary to immobilize the patient and assist the surgeon. A tourniquet was placed around the limb to control blood-flow. Two circular incisions were made, one through the flesh down to the muscles and the other through the muscles to the bone. A retractor was placed over the exposed bone and the soft tissues pulled up and away. The bone was sawed through as close to the retractor as possible. This part of the operation would be completed in one to two minutes. Next, the soft tissues were relaxed over the stump of the bone, the

blood vessels closed with needle and thread, and the wound dressed and bandaged. Closure by cautery was no longer the preferred method of securing the wound. Medications for pain and fever were administered as necessary.

Lithotomy—The set of curved utensils in the case in the back room were for lithotomy that is finding and removing stones from the urinary bladder, a condition found more commonly in men than in women. The long curved tool was known as a urethral sound or dilator. It was introduced into the urethra up to the bladder to locate the stone. An incision was then made "on the gripe" (the skin area above the scrotum and below the anus). The stone was removed through this opening with forceps. The wound

was closed, and again medications were administered as needed.

Midwifery—In the 1750s the presence of a male authority in the birthing chamber was gaining more acceptance. Five doctors in Williamsburg have been identified as man-midwives, including Dr. John M. Galt whose account books contain several entries in which he attended women in labor.

Other Shop Business—In addition to medical supplies and services, many doctors supplemented their income by selling various and sundry items. Drs. Pasteur & Galt advertised in the *Virginia Gazette* such articles as tobacco and snuff, gold and silver leaf, isinglass, vermicelli, and French chalk for taking grease out of the silks and fine cloths.



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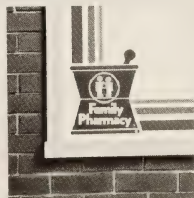
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Dementia and Alzheimer's Disease

Peter P. Lamy, Ph.D., Sc.D.

The Disease: Disorders causing dementia—the loss of mental functions in an alert and awake individual—will constitute a large and growing public health problem until well into the next century. Today, an estimated 1.5 to two million Americans suffer from severe dementia. They are so incapacitated that others must care for them continually.

In addition, one to five million have mild or moderate dementia (1). Ten times as many people are affected now as were at the turn of the century (2). The incidence at age 65 is one in ten, and increases to approximately one in three by age 85 (3). It is currently listed as the fourth leading cause of death, behind heart disease, cancer, and stroke (4). The number of people with severe dementia is expected to increase 60% by the year 2000. Unless cures or means of prevention are found, 7.4 million Americans will be affected at the beginning of the next century. Once Alzheimer's disease begins to progress, the projected life span of the individual is reduced substantially. The overall rate of progress is approximately 4.1 blessed points per year, with neither age of onset, duration of illness, nor family history having a significant influence on the rate of progression (5). The disease progresses insidiously, eventually destroying the functional capacity of the brain. This is first manifested in loss of memory and in other cognitive disturbance. Eventually it progresses to the point where its victims are unable to perform even the simplest task and can no longer care for themselves (6). Dementia, especially Alzheimer's disease, is considered to be the number one health problem by the National Institute on Aging (7).

Disruptive Behavior: Disruptive behavior is not necessarily "psychiatric" behavior, as the differentiation between behavioral and cognitive symptoms is arbitrary. "Inappropriate" behavior may result from neurological illness or from the fact that persons cannot communicate their feelings, cannot help themselves, or even do not know who they are. These persons may present with depression, fear, anxiety, or anger. Behavioral or psychiatric symptoms include angry outbursts, depression, violence, apathy, stubbornness, resistance to care, suspicion, accusations, incessant repetition of the same question, use of obscene language, talking to deceased relatives, hallucinations, delusions, stealing, getting lost, hiding things, paranoia, and uncooperativeness (8,9). Agitation may be encountered manifesting as

aggressive behavior, verbal agitation, or in a nonaggressive manner, via pacing and general restlessness (10). Cognitive impairment and dementia have also been linked with sleep disturbance (11).

Antipsychotics are often used to manage these problems (12). It is important to recognize that patients with an impaired central nervous system will be especially sensitive to the action of these drugs, and these drugs can worsen many intercurrent medical problems. Side effects range from tardive dyskinesia, falls and subsequent fractures, hepatotoxicity, sexual dysfunction, ocular changes, dermatological problems, to agranulocytosis.

Yet of the literally thousands of studies investigating the effectiveness of antipsychotics in addressing the behavioral pathology of Alzheimer's disease, only nine were placebo-controlled (13–21). These studies documented a high placebo effect, indicating that a majority of patients may have slight or moderate, but not dramatic improvement, and that a large percentage of patients show no change or even behavioral deterioration with treatment. The core cognitive symptoms of dementia and their related effects apparently do not respond to antipsychotic treatment and may, indeed, be worsened. On the other hand, suspiciousness, excitement, hostility, irritability, emotional lability, uncooperativeness, hallucinations, delusions, insomnia, verbal aggression, agitation, and anxiety may respond to acute use of these drug (22).

The Caregiver: Care of the cognitively impaired patient is most stressful, and even more stressful is care for patients with mental impairment overlaid with disruptive behavior. Alzheimer's patients demand substantial and constant supervision. Not surprisingly, caregivers of dementia patients report the highest level of chronic fatigue, anger, depression, family conflicts, and loss of friends and hobbies. They also report a very high use of drugs, particularly psychotropic drugs (23). Thus, in addressing the needs of the Alzheimer's patient, health care providers must learn to understand and address the needs of the caregiver.

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USP Says Thank You to the Maryland Pharmacists Association



On March 8, 1991, the Maryland Pharmacists Association was presented with a certificate of appreciation in recognition of pharmacists' 20 years of cooperation and support to the USP Drug Product Problem Reporting Program (DPPR). The presentation was made to Dave Miller, Executive Director, by Diane M. McGinnis, Director of the DPPR Program, at the 138th Annual Meeting of the American Pharmaceutical Association in New Orleans.

Through the cooperative efforts of the association and USP over the last two decades, the pharmacists in Maryland have responded to the need to identify hazardous products and to improve USP drug product standards by reporting to DPPR. Pharmacists in all states have submitted 80,000 drug product problems since 1971 and all state pharmacy associations have played a major role in the Program's success.

In addition to distributing the report forms and publishing the Program's 800-number, the associations have sought to provide feedback and educate pharmacists by reproducing the *USP Drug Product Quality Review* in their publications. The *Review* relates regulations and standards to the most frequently asked questions on drug quality that are received through the Program.

The USP encouraged the associations to carry on their support of the DPPR Program so that pharmacists will continue to impact drug quality into the 21st century.

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Investing for Today

Financing Your Children's Education: Have You Done Your Homework?

Daniel K. Hays

Whether you have tots or teens, planning for their education can be a worry, especially when you consider the facts.

Startling Statistics

In the last 10 years, the increase in college costs has outstripped inflation by two percentage points each year.

This means that in the next year, the average student will pay 7% more for tuition and costs. At that rate, a four-year degree at a public college or university will cost nearly \$50,000 by the year 2000, and the same degree at a private university could reach the \$160,000 mark.

Suppose you want to accumulate \$50,000 by the year 2000. You would have to invest \$3,618 a year for the next 10 years (assuming a 7% after-tax rate). If you delay starting to save until 1993, you would have to set aside \$5,777 a year. To accumulate \$160,000 by the year 2000, assuming the same after-tax rate, you would have to invest \$11,580 a year for the next 10 years. And if you wait until 1993 to begin saving, the amount needed jumps to \$18,488 per year.

Custodial Accounts Affected

To make matters worse, tax reform negatively impacted the most common tax-advantaged methods of saving for college: custodial accounts established under the Uniform Gifts to Minors Act and Clifford trusts. While the maximum contribution to a custodial account remains at \$10,000 per person per year without incurring gift taxes, the taxes on earnings have changed. Under the new laws, children under the age of 14 are taxed at their parents' presumably higher rate if they have unearned income over \$1,000. For children under 14 years of age, the first \$500 of unearned income counts as a standard deduc-

tion and the second \$500 is taxable at the 15% rate. Children over the age of 14 are taxed at their own tax bracket.

Clearly, the importance of planning ahead cannot be overemphasized whether you're just starting a college savings plan or are already meeting tuition payments.

Depending on your tax bracket and the age of your children, there are a number of investments to consider.

Tax-Advantaged Alternatives

Income generated for children younger than age 14 in custodial college fund accounts should include tax-exempt and tax-deferred securities.

Zero-Coupon municipal bonds are well-suited to saving for college because they allow for accurate planning of expenses. Zeroes purchased at a deep discount from face value and a maturity date that coincides with the time your child is ready for college can appreciate in value tax-free, assuring that the money will be available when you need it.

DINTS (Deferred Interest Securities) are a select group of corporate zero coupon bonds that defer tax liability until the issues are sold, called or mature. DINTS compound tax-deferred so the eventual taxes will probably be paid at the child's lower tax bracket, resulting in a higher after-tax yield.

Taxable Investments

For investors who are less concerned about tax ramifications, the following instruments may be of interest.

STRIPS (Separate Trading of Registered Interest and Principal Securities) are component parts of United States Treasury notes and bonds that sell at a discount from face value and pay only principal at

maturity. These issues are available every three months up to 30 years, which means you can create a lump sum payment that would mature all at once or you could stagger maturities to provide periodic distributions for education expenses. Treasuries by themselves may be another option to consider.

Growth-oriented mutual funds and unit trust investments are worth considering if your resources are limited. Both alternatives offer the benefits of investing in diversified portfolios to reduce risk, the opportunity to compound reinvested earnings and the ability to set up an investment that pays a specific income on a regular basis.

Stock investments may be your choice if you have time to save and prefer an aggressive strategy aimed at capital appreciation.

Certificates of Deposit or other conservative fixed-income vehicles are appropriate if you're faced with college tuitions within the next year or two.

Another Alternative

Suppose your child is ready to enter college immediately. You've been putting money away but you're still short of funds to meet tuition payments. A home equity loan is an inexpensive way to borrow money. Rates are generally low, your loan is secured by your mortgage, and the funds you borrow are tax deductible when used for education purposes.

To complete your homework on ways to fund your children's education, consult your financial adviser. He or she can help you determine the best method of meeting your objective.

So . . . seize the day!

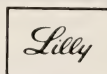
Daniel K. Hays is a financial consultant with Advest, Inc. in Lutherville, Maryland. If you have any questions, he can be reached at 800/272-7368.

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First DataBank Reports 1990 Price Changes

First DataBank, the leader in supplying electronic drug information, has released its annual review of drug price changes.

In 1990, the top 200 drugs (by prescriptions filled), the top 50 drugs (by prescriptions filled) and single source products showed price increases above the average for all drugs.

Anti-ulcer treatments, tranquilizers, high blood pressure medications, and cardiac drugs were the major therapeutic classes with the largest therapy increases in 1990.

General Trends

Pharmaceutical prices changed an average of 7.7 percent for the calendar year ending December 31, 1990. Just under 40 percent of all federal legend drug products had price changes, and the average product that changed had a 19.6 percent increase.

The most widely used products had more dramatic price increases. The American Druggist Top 200 Drugs, which account for over 50 percent of all prescriptions dispensed, went up an average of 10 percent. Of these products, almost three-quarters (74 percent) had price changes, and those that changed increased an average of 13.5 percent. The Top 200 products include over 1,500 package size and strength combinations and account for just under 4 percent of the total number of products on the market and 7.46 percent of all changes.

The Top 50 products went up an average of 11.2 percent, with over 90 percent of the Top 50 products hav-

ing price changes. Those Top 50 products that changed went up, on average, 12.4 percent. The Top 50 products represent 31 percent of all dispensed prescriptions and, with over 450 package size and strength combinations, make up one percent of the total number of products on the market and accounted for 2.8 percent of price changes.

Single source products (those products with only one manufacturer and distributor) also had larger increases than the industry average. Single source items went up an average of 8.81 percent. Over 70 percent of single source items had price changes and the average product went up 12.5 percent. The 2,690 single source products represent 7.1 percent of all products but accounted for 12.8 percent of all changes.

Therapeutic Classes

GI products led the major therapeutic categories with the largest average price changes. This class of products, which includes H₂-Antagonists, had an average increase of 24.9 percent. Of the 194 products on the market throughout 1990, 46.4 percent had price changes and the average increase was 53.6 percent.

Tranquilizers had average price increases of 11.3 percent. Of the 2,011 products on the market in 1990, 40.6 percent had price increases and the average increase was 27.7 percent.

Vasodilator agents had average price increases of 10.1 percent. Of the 1,268 products on the market

35.3 percent had changes and the average increase was 28.5 percent.

The AHFS class of cardiac drugs had average price increases of 9 percent. Of the 1,557 products on the market 44.4 percent had price changes and the average increase was 20.3 percent.

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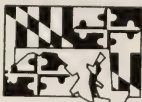


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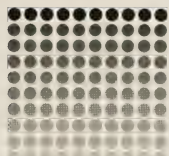


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Sesquicentennial Highlights

Part of a continuing series looking back on Maryland pharmacy in honor of the 150th Anniversary of the University of Maryland School of Pharmacy.

The Founding of MSHP

by Norman Pelissier

On the evening of March 25, 1944 a group of fifteen hospital pharmacists met at the Maryland General Hospital in Baltimore. The group's first order of business was to decide its geographic scope and what name it would adopt. Three possibilities were considered: 1) creation of a local group for hospital pharmacists in Baltimore, 2) creation of a state group of hospital pharmacists, and 3) creation of a combined Maryland-District of Columbia group of hospital pharmacists. Following some discussion a vote was taken and the consensus was that the group would represent the state hospital pharmacists and thus the name "The Maryland Association of Hospital Pharmacists" was adopted by the group.

So reported secretary-treasurer Harriett R. Noel in the first recorded minutes of this group. Also at that first meeting, a Constitution and Bylaws was adopted and officers of the Association for the 1944-1945 year were elected.

A second meeting was held at Sinai Hospital on April 29. The topic of discussion centered on the procurement of certain scarce chemicals (due to the War) such as triethanolamine, glyceryl mono-stearate, menthol, thymol, ethyl alcohol and isopropyl alcohol. This meeting, like those held the first several years of the Association's existence, was held on a Saturday night. Meetings generally began at 7:30 p.m. and often did not end until after 11:00

p.m. Attendance normally consisted of ten to twenty members.

The Association's third meeting was held on July 29 at the Women's Hospital. This hospital located at Lafayette and John Streets was to become the Greater Baltimore Medical Center in 1964. The group voted to contact all hospital superintendents throughout Maryland by letter asking them whether or not the people employed by them to handle drugs were pharmacists. The fourth meeting, held on November 18, was held in the amphitheatre of the University of Maryland Hospital. This was the first meeting at which an outside speaker was invited to talk to the group. Nineteen members and 23 invited guests were present. The speaker was Dr. Russell Nelson of the Johns Hopkins Hospital who spoke on "The Newer Aspects of Penicillin." Dr. Nelson mentioned a newer discovery, streptomycin, which showed promise of being effective against gram-negative organisms. A program committee was appointed consisting of Mrs. Angela Allen, Mr. Alexander O'Grinz, and Mr. Milton Skolaut.

The fifth meeting of the Association was held in Hurd Hall of the Johns Hopkins Hospital in January of 1945. Dr. John C. Krantz, Jr., Professor of Pharmacology at the University of Maryland School of medicine, spoke on "The Newer Developments in Volatile Anesthetics." He discussed the two anesthetics in common use at that time,

ether and cyclopropane. Mr. Alperstein reported on correspondence with the American Society of Hospital Pharmacists, inquiring whether this recently formed group was affiliated with the American Pharmaceutical Association or the American Hospital Association. The response from ASHP indicated that it was affiliated with the American Pharmaceutical Association.

On March 24, 1945 the Maryland Association of Hospital Pharmacists observed its first anniversary in the Board Room of the Union Memorial Hospital. Nominations were presented for candidates for office for the following year. The results of a mail ballot election were announced at the Church Home and Hospital on April 28.

President Skolaut presided at the meeting held on February 9, 1946 at Women's Hospital. A discussion was held on whether all members leaving the organization would become honorary members. It was reported that new regulations required separate fire-proof storage facilities for alcohol.

The next meeting was held on May 11, 1946 at the Memorial Hospital in Cumberland. A discussion was held as to the need of a pharmacist at Franklin Square Hospital. On June 16, the Association met at Mercy Hospital. Captain Monroe Romansky of Walter Reed Hospital spoke on "Penicillin." At the September 21 meeting held at Baltimore City Hospital, Dr. Purdum reported

on his attendance at the ASHP Institute held in Ann Arbor, Michigan. On January 11, 1947 the MAHP met at the West Baltimore General Hospital. A film on "The Use of Amino Acids in Surgery" was shown. At the meeting held on February 24, 1947 at the Johns Hopkins Hospital, nominations were presented for new officers.

Dr. Purdum suggested that the Association form a journal club "to make reports at meetings on any articles that would have been read that would be of interest to other members." At the December 13, 1947 meeting held at Women's Hospital, Dr. Purdum was congratulated on being elected President of the ASHP. The question of ASHP affiliation was discussed at this meeting but no conclusion could be reached. It wasn't until March 5, 1949 that an amendment was passed to limit membership to active and associate members in order that the Association could become affiliated with the ASHP. Apparently, the MAHP became affiliated with the ASHP that year.

New meeting sites of the Association included the Nurses Home of St. Joseph Hospital, March 5, 1949; Franklin Square Hospital, January 21, 1950; the U.S. Marine Hospital (which later became the USPHS Hospital), May 26, 1951; and the Medical Supply Depot, USPHS, Perry Point, Maryland, December 10, 1952. Herbert Flack and several of his pharmacy interns from the Jefferson Medical College were

guests at this latter meeting.

The MAHP met at the Kelly Memorial Building on February 18, 1953. Greetings were extended by Mr. Joseph Cohen, Executive Secretary of the Maryland Pharmaceutical Association. Dean Noel Foss addressed the Association at a meeting held on April 25, 1953 at the University of Maryland School of Pharmacy. Mr. Richard Crane of Armour Laboratories presented a film on the product Tryptar.

Internship requirements for pharmacist registration were discussed at the March 17, 1960 meeting of the MAHP held at the Johns Hopkins Hospital. President Statler reported on his meeting with Mr. Francis Ballassone, secretary of the Maryland Board of Pharmacy. Prior to registration in Maryland, a pharmacist must work in a pharmacy for one year, four months of which must occur after graduation. A maximum of six months credit can be received for working in a hospital pharmacy. It was a unanimous decision on the part of the members present to press for full credit for hospital pharmacy experience.

Mr. Neil Davis, Director of Pharmacy Services at the Jefferson Medical College, Philadelphia, spoke on "A Pharmacy and Nursing Committee" at the June 15, 1961 meeting of the MAHP held in the Gordon Wilson Hall, University Hospital. This was a joint meeting held with the Maryland League for Nursing.

During the 1960's there was a close association between the Mary-

land group and the District of Columbia hospital pharmacist's group. Installation of officers was generally a joint affair held at the Walter Reed Army Hospital and a number of meetings were held at the National Institutes of Health and the Bethesda Naval Hospital. The Association had just over 100 members in 1962. This included 65 active members, 34 associate members and 2 interns. Attendance at meetings, however, was generally quite low.

The Maryland Association of Hospital Pharmacists was to undergo a lot of changes during the 1960's. In 1966 the Association's name was changed to the Maryland Society of Hospital Pharmacists and the first annual Hospital Pharmacy Seminar was held that year in Ocean City with President Sydney Burgee in office. Attendance at meetings began to increase. The Society became officially incorporated in 1969. At the February 12, 1970 meeting, President Samuel Lichter made note of the incorporation and announced that the Society's bylaws would be revised in order to apply for tax-exempt status. The Society's first Newsletter, edited by Norm Pelissier, made its appearance in October, 1969. This was also the year that the Society approved its first dues increase (from \$3.00 to \$10.00). And in 1968, work began on what was to become the Society's longest undertaking, the "Suggested Principles and Guidelines for Pharmacy Services in Hospitals."



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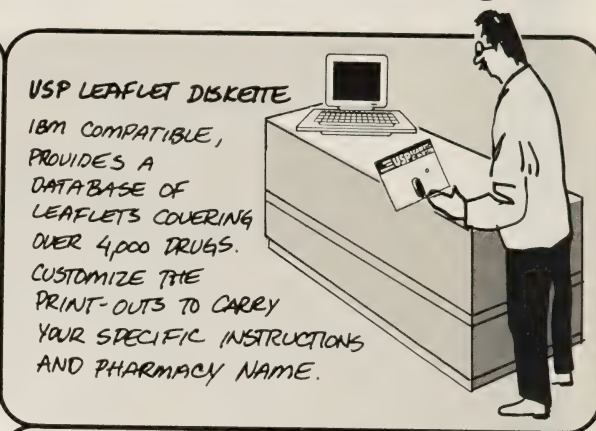
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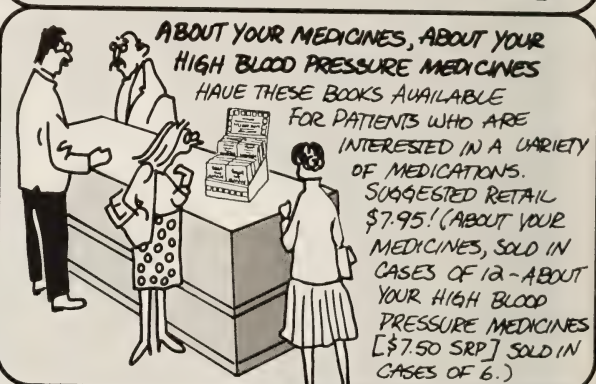
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MPhA members visit a Swedish pharmacy during the MPhA trip to Scandanavia this past January.



MPhA President Mark Levi and Convention Chairman Elwin Alpern shown here with the President of Novo Nordisk. Thanks to Novo Nordisk representative Jack Peters, our group was provided with luncheon and tour of the company's facilities.



Touring a Scandanavian Apothecary are Mark Levi, Paul Miller, Irv Yospa, Birgitta Davidson—Director of International Relations with the Apotecksbolaget—Stan Smith, Dorothy Levi, and Elwin Alpern.



Visiting the Danish Pharmaceutical Association are Elwin Alpern, Stan Smith, Dorothy Levi, Bente Frekjaer—on staff with the DPA, Irv Yospa, and Mark Levi.

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Continuing Education Quiz

The Maryland Pharmacist **JULY 1991**

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by November 30, 1991. A continuing education certificate for one contact credit will be mailed to you within 30 days. Please type or print clearly.

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Is this program used to meet your mandatory CE? ☐ Yes ☐ No

Did this article achieve its stated objectives? ☐ Yes ☐ No

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Parkinson's Disease

1. Bradykinesia that occurs in Parkinson Disease refers to:
 - a. excessive movement.
 - b. obsessive movement.
 - c. slowed movement.
 - d. uncontrolled movement.
2. Which of the following drugs is most likely to affect the action of monoamine oxidase?
 - a. Amantadine
 - b. Bromocriptine
 - c. Pergolide
 - d. Selegiline
3. Antidyskinetics used in treatment of parkinsonism-induced tremor reportedly block receptors sensitive to which of the following neurotransmitters?
 - a. Acetylcholine
 - b. Dopamine
 - c. Norepinephrine
 - d. Serotonin
4. Levodopa is the metabolic precursor of:
 - a. carbidopa.
 - b. dopamine.
 - c. levonorepinephrine.
 - d. dopa decarboxylase.
5. Patients taking high doses of which of the following therapeutic agents are most likely to require concomitant administration of drugs that attenuate Parkinson-like symptoms?
 - a. Antidyskinetics
 - b. Monoamine oxidase inhibitors
 - c. Phenothiazines
 - d. Tricyclic antidepressants
6. The dietary component that is most likely to alter levodopa efficacy is:
 - a. amino acids.
 - b. carbohydrates.
 - c. fiber.
 - d. triglycerides.
7. Of the following actions, the goal of therapy of treating patients with parkinsonism is to decrease:
 - a. cholinergic activity.
 - b. dopaminergic activity.
 - c. histaminergic activity.
 - d. serotonergic activity.
8. Patients taking which of the following drugs should be counseled NOT to exceed the prescribed dose of 5 mg twice a day?
 - a. Amantadine
 - b. Diphenhydramine
 - c. Pergolide
 - d. Selegiline
9. Drugs that cause a "Parkinson-like" syndrome are most likely to do so because they deplete or interfere with action of:
 - a. acetylcholine.
 - b. dopamine.
 - c. epinephrine.
 - d. serotonin.
10. The concentration of MAO-B in the brain can be estimated by measuring its level in:
 - a. granulocytes.
 - b. leukocytes.
 - c. macrophages.
 - d. platelets.

Classified

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"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Horn and Horn Smorgasboard on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (301) 358-7036.

FREE CLASSIFIEDS. MPhA members may place a classified ad at no cost in the journal. Send your type-written ad to 650 West Lombard St., Baltimore, Maryland 21201.

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THINKING OF RETIRING? Motivated, energetic pharmacist looking to buy a profitable retail pharmacy. Some owner financing is desired. Please contact through the MPhA office at (301) 727-0746.

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PHARMACISTS REHABILITATION COMMITTEE HOTLINE is (301) 727-0746.

LOOKING FOR AN OLD TIME PHARMACY? Late 1800's apothecary on O'Donnell Square in Baltimore, currently operating as a soda fountain and gift shop, with original wooden shelving, mirrors, marble, and fountain set-up is for sale by its current owners. The shop has been featured in a number of articles as well as on television. This is a rare opportunity to own a piece of pharmacy history. For more information, call Linda Smit at (301) 667-0653 or (301) 675-0059.

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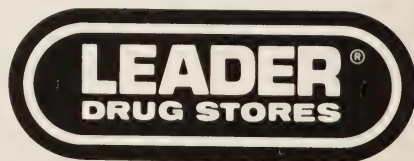


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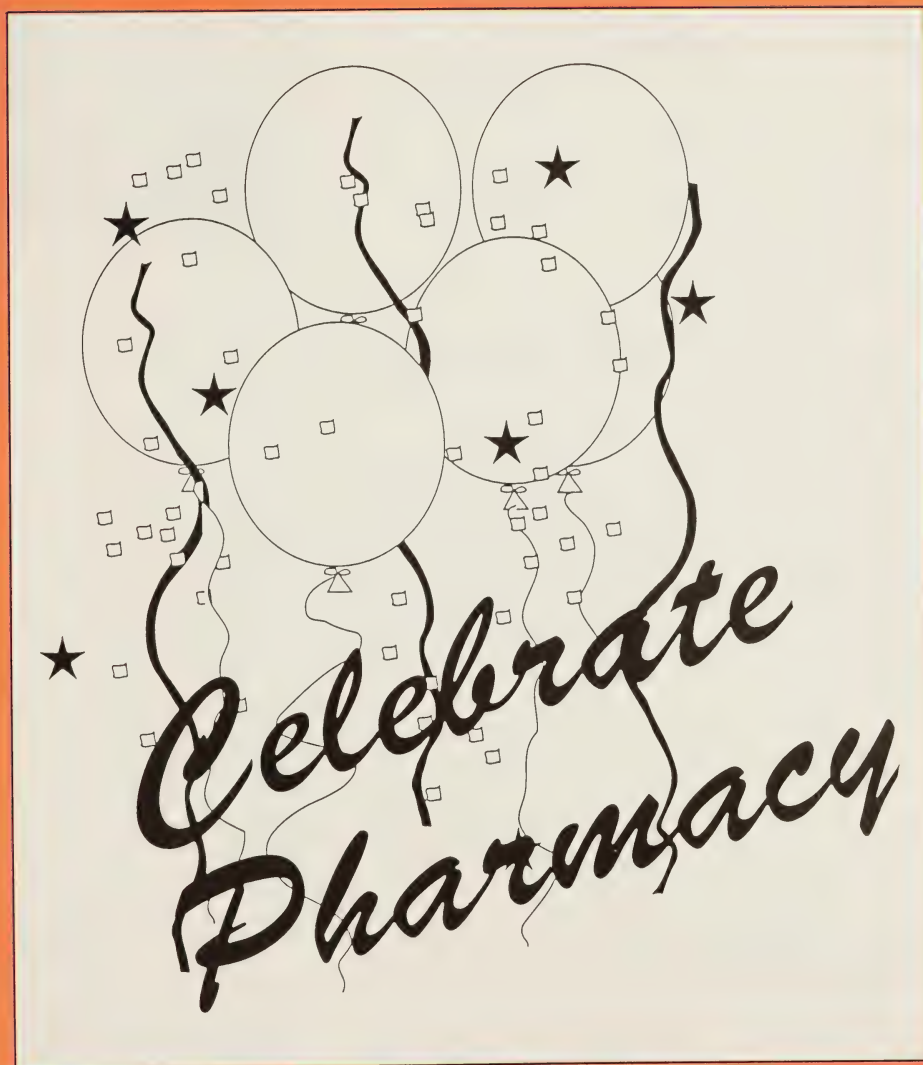


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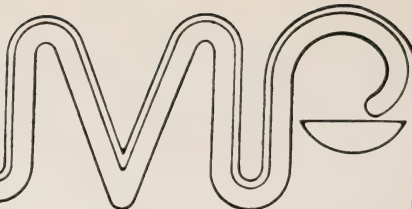
VOL. 57

August, 1991

No. 8



*Reports from the 109th
Annual MPhA Convention*



AUGUST 1991

VOL. 67

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A Great Return on Your Investment

Why should I pay my MPhA dues? Will I get a return on my investment?

Well, if you are reading this column in your own copy of the *Maryland Pharmacist*, you have made a decision that MPhA dues are a good investment. But you have probably run into colleagues who are not MPhA members, asking, "What's in it for me?"

You should expect certain products from your professional association, and MPhA has delivered. For example, we employ a professional lobbyist, which has enabled MPhA staff and volunteers to pass Maryland legislation favorable to pharmacy. The Association is in the process of publishing the Pharmacy Law Book, in cooperation with the Maryland Board of Pharmacy. MPhA is spearheading the development of voluntary pharmacy practice standards. Our Member Services Committee, under the leadership of co-chairpersons Ellen Yankellow and Howard Schiff, includes the Rehabilitation Committee, continuing education, group insurance and up-to-date publications that give members information on third party plans, drug recalls, and continuing education.

These are all valuable dividends as a result of joining MPhA. However, the most important return on your investment is your ability, as a member, to prescribe changes or improvements in the profession. As an association member, you have a voice. You can call upon MPhA staff or officers for information and action. You can even be a delegate in the MPhA House of Delegates and vote on policy issues.

So, the next time the pharmacist working with you asks, "Why should I spend money on MPhA dues?", show him or her a copy of this journal, or the law book, or the latest MPhA continuing education brochure. Better yet, ask him to look around and see how pharmacy practice has strengthened over the years.

Ilene Zuckerman, Pharm.D.

MPhA President

Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Correspondence Course

Sunburned Skin: Treatment with OTC Products

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

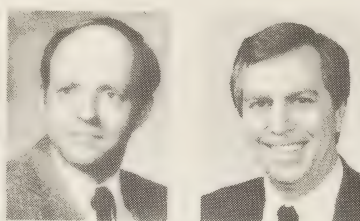
The goals of this lesson are to discuss skin changes that occur with sunburn, and the treatment used for self-therapy of sunburned skin.

Objectives

At the conclusion of this lesson, participants should be able to:

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1. identify specific portions of ultraviolet radiation associated with burning and tanning;
2. select specific pathologic changes and symptoms of sunburned skin;
3. choose important pharmacologic and toxicologic aspects, uses and misuses, and appropriate warnings associated with ingredients of OTC products used to treat symptoms of sunburn; and
4. choose from a list, important points to convey to patients about safe use of OTC sunburn remedies.

Sun worshiping is a national pastime for many Americans, even though they are advised to avoid excessive contact with solar radiation. As a result of their overzealous exposure, millions suffer from sunburn each year. Most acute dermal damage is self-limiting and causes little more than minor discomfort. The majority of these conditions are self-treatable. But some injuries may be extremely painful, and require physician intervention and intense therapy. And, there is convincing evidence that solar damage is cumulative over a lifetime such that serious pathology can result later in life, as a result of dermal changes acquired years earlier.

The pharmacist is often the first person to be consulted on how to treat sun-damaged skin, or answer questions that are posed in the popular press about long-term exposure to sun.

This month's lesson helps answer those questions and discusses OTC

products used to treat sunburn-injured skin. Physiologic reactions to sunburn are also explained to facilitate understanding of these products and other therapies.

Burns

More than two million Americans sustain serious burn injury each year. Approximately 100,000 require hospitalization, with about 10,000 succumbing to their injury. While burns result from many causes (i.e., contact of the skin with heat, electricity, infrared and ultraviolet solar rays, ionizing radiation, and chemical agents), most mild burns are triggered by overexposure to ultraviolet rays of the sun. Most severe burns are caused by heat from flames, hot liquids, or direct contact with hot objects.

The direct outcome of burn injury is coagulation of dermal protein resulting in tissue necrosis. This destroys the skin's ability to fulfill its many functions.

Burns are categorized as first, second, or third degree with differentiation based mainly on the size of the area affected, and depth of the wound. Sunburn injury may be first or second degree.

First degree burns are treatable on an ambulatory basis. There is generally only superficial epithelial cell damage exhibited by localized areas of redness, which blanch to white on pressure, due to the body's normal inflammatory response to injury. Scarring does not occur with first degree burns and they generally heal within three to four days.

Second degree burns can be caused by excessive sun exposure, contact with hot objects for a short period of time, short blasts of intense heat, and boiling water. Second degree burns destroy the affected epidermis and may damage the upper level of dermis. They are characterized as weeping, blistering, beefy-red wounds. Pain receptors and nerve fibers are

generally intact, and there is pain upon touching the wound. If skinned appendages (e.g., hair shafts, sweat and sebaceous glands) remain intact and infection is prevented, spontaneous healing and regeneration is possible. With proper care, the healing process usually takes about a month.

Third degree burns result from prolonged exposure to intense heat, flames, electricity or chemicals, or emersion in scalding liquids. The entire epidermis and dermis are destroyed, as are all skinned appendages, along with varying amounts of subcutaneous fat and muscle. Since the sensory nerves are destroyed, third degree burns are painless and unresponsive to touch. Because the skinned appendages have been destroyed, regeneration of epithelium and spontaneous wound healing are rare. Skin grafting is often necessary to completely heal the wound.

It is generally held that first degree burns are self-treatable. Second degree burns on less than 15% of the body, or third degree burns on less than 2% (depending on the area involved) can be treated on an ambulatory basis with medical supervision. Second degree burns greater than 15%, or third degree burns greater than 2% of the body's surface, require hospitalization and rigorous treatment.

The Sun as a Source of Skin Damage

Much of the sun's energy that reaches the earth's surface on a cloudless day is ultraviolet (UV) radiation of the UV-A spectrum. About 10 percent is UV-B. UV-A radiation is also designated "tanning," and UV-B, "burning," rays.

At any given point on the planet, the sun is most directly overhead between 10:00 a.m. and 2:00 p.m. Here, solar rays travel a shorter distance through the stratosphere, and are least absorbed by the earth's ozone layer. The amount of UV energy that reaches the surface decreases when solar rays are filtered through clouds. UV-B is about 1000 times more potent than UV-A in promoting burning. Therefore, most damage from burning is from UV-B rays.

Sunburn damage occurs to the greatest extent during the summer months. But sunburn is also possible during winter, especially at high altitudes. The intensity of UV light increases approx-

imately four percent for each 1000 ft elevation above sea level. At 6000 ft, for example, solar UV energy is increased 24 percent compared to sea level.

Direct exposure to UV rays is not required to sustain burning. Light, shiny surfaces reflect UV light: white sand up to 25 percent; white painted surfaces and snow, shiny metal surfaces, and city pavements up to 70 percent; and water nearly 100 percent when the sun is directly overhead. Thus, even when protected from direct exposure to overhead rays by an umbrella or hat, reflected UV rays can still cause damage.

Melanin. The amount of UV radiation that penetrates the skin and, hence, the degree of sunburn injury, are inversely proportional to the concentration of melanin in the dermis. Melanin pigments are formed by specialized cells, melanocytes, in the basal layer of skin in response to UV radiation. They migrate upward to impart a tanned appearance to the skin. Tanning helps protect the skin from further injury. Fair-skinned individuals burn more easily than persons with darker complexions, because they have fewer melanocytes and, therefore, less inborn protection.

Solar radiation enhances cell division rate of epidermal cells. This promotes thickening of the stratum corneum in about 4 to 7 days, making the skin even more impervious to penetration by UV radiation. Thus, persons who are exposed to non-burning concentrations of sunlight over prolonged periods will therefore be partially protected from burning.

Reaction to Sunburn. The body's natural reaction to sunburn includes early inflammation with edema due to infiltration by lymphocytes, endothelial swelling, and capillary leakage of erythrocytes. Histamine, liberated in skin, is responsible for the early phase of the sunburn reaction. Histamine concentration returns to normal within 24 hours; therefore, it is generally accepted that there are other mediators responsible for the latter phases of sunburn injury.

Prostaglandins (PG) of the PGE and PGF series are commonly implicated chemical mediators of the delayed erythema (redness) reaction that follows within 14 to 20 hours after exposure, and persists 1 to 3 days. Evidence favoring this hypothesis includes:

- (1) PGs are synthesized in human skin;
- (2) their levels increase after UV irradiation;
- (3) sunburn blister fluid contains significantly elevated PGE₂ concentration;
- (4) exogenously administered PG causes erythema at the site of injection; and
- (5) blocking PG synthesis with indomethacin and other inhibitors of their synthesis may significantly attenuate the sunburn reaction.

Symptoms

The first manifestation of sunburn is a pink or scarlet discoloration of the skin in Caucasians, along with mild edema. This may progress to bright erythema with intense edema and/or blistering, depending on the extent of injury. The skin will be tender, warm and taut if the burn is mild. Itching is common, and is the major symptom for which consumers seek relief. The area may be extremely painful if injury is severe.

Within 12 to 24 hours, pain, tenderness and erythema are usually maximized. The skin may blister or peel in one to several days with severe injury, and the victim may experience nausea, chills and fever, and tachycardia.

Acute, uncomplicated sunburn heals without scarring. If secondary infection develops, scarring may follow. Infection is difficult to treat because damaged skin provides an excellent medium for microbial growth. When the underlying vasculature has been damaged, tissue is also less capable of protecting itself. Early colonization is chiefly by Gram-positive bacteria (e.g., staphylococci, streptococci). By the third day post-irradiation, the flora changes to primarily Gram-negative organisms (e.g., pseudomonas, klebsiella, proteus) and fungi (candida). Left unchecked, these pathogens can invade underlying and adjacent healthy tissues, and possibly gain entry into the general circulation.

Chronic exposure to UV radiation, especially in light-complexioned persons, causes fine wrinkling of the skin, and basal cell and squamous cell cancer. It may also be a risk factor for malignant melanoma.

Treatment of Sunburn

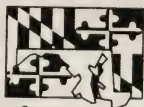
Mild sunburn, or burn damage from other sources, responds to treatment with OTC products (Table 1). When

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Table 1			
Representative OTC Products For Treating Sunburn			
Product (Mfr.)	Dosage Form	Anesthetic	Antimicrobial
Americaine Anesthetic (Fisons)	Ointment, Aerosol	X	
Bicozine (Creighton)	Cream	X	
Butesin Picrate (Abbott)	Ointment	X	
Dermoplast (Wyeth/Ayerst)	Lotion, Aerosol	X	
Foille (Blistex)	Ointment	X	X
Foille Plus (Blistex)	Aerosol	X	X
Foille Medicated First Aid (Blistex)	Ointment, Aerosol	X	X
Medicone Dressing (Medicone)	Cream	X	X
Medi-Quik (Mentholatum)	Aerosol, Pump spray	X	X
Nupercainal (Ciba)	Cream, Ointment	X	
Pontocaine (Winthrop-Breon)	Cream, Ointment	X	
Prax (Ferndale)	Cream, Lotion	X	
Rhulicaine (Rydelle)	Solution	X	
Solarcaine (Plough)	Cream, Lotion, Aerosol	X	X
Surfadil (Lilly)	Lotion	X	
Tronothane (Abbott)	Cream, Jelly	X	
Unguentine (Mentholatum)	Ointment, Aerosol	X	
Xylocaine (Astra)	Ointment	X	

extensive blistering, extreme erythema and/or pain are present, affected persons should be referred to a physician.

Counterirritants. Counterirritants (camphor, menthol, phenol) partially relieve dermal discomfort by stimulating cutaneous cold receptors. Their exact antipruritic mechanism is unknown, but overriding the lower level of itching (mild inflammation of pain receptors) is thought to be contributory. Counterirritants may irritate burned areas, and therefore, should not be used on these lesions.

Protectants. Minor burns often re-

spond satisfactorily to a skin protectant (Table 2). These add moisture to the skin to help reduce dryness, and/or lubricate it to minimize further damage from friction by clothing and bed sheets.

Local Anesthetics. Most OTC sunburn remedies contain a local anesthetic. They interfere with the generation and transmission of nerve impulses by affecting the transport of sodium and potassium across cell membranes.

Local anesthetics are poorly absorbed across unbroken, intact skin. When applied to small, localized areas, the amount absorbed is not sufficient-

ly significant to cause systemic reactions. Applied to large areas of damaged skin, however, they may be absorbed sufficiently to initiate toxicity.

Initial symptoms of toxicity are characterized by central nervous system stimulation followed by depression. Cardiovascular functions may also be depressed, resulting in reduced cardiac output, and hypotension with shock. Pramoxine and dyclonine do not cause systemic toxic sequelae characteristic of "caine"-type local anesthetics. They may depress cardiac function, but they do not significantly stimulate the CNS.

Local anesthetic action persists approximately 30 to 45 minutes following topical application. They should not be applied more frequently than four times daily. Use is ideally reserved for periods when pain and/or itching are particularly bothersome, such as in the morning, at bedtime, and other quiet times of the day.

Local anesthetics should not be recommended for severe burns, as they may prolong the time before a burn victim will contact a physician. Table 3 lists local anesthetics that are safe and effective for OTC self-treatment of sunburn pain.

Antihistamines. Antihistamines block attachment of histamine to its physiologic receptors and, therefore, help control itching. Their mechanism of action is uncertain. They possess weak local anesthetic action when applied topically, and benefit is probably due to this action upon dermal sensory receptors.

Hydrocortisone. This drug has been available without prescription in

Table 2

OTC Skin Protectants For Sunburn

Agent	Concentration (%)	Moisturizes	Lubricates
Allantoin	0.5-2.0	X	
Cocoa butter	50-100	X	X
Dimethicone	1-30	X	X
Glycerin	20-45	X	
Petrolatum	30-100	X	X
Shark liver oil	3	X	X
Zinc carbonate	0.2-2		X
Zinc oxide	1-25		X

Table 3

Safe and Effective Local Anesthetics for OTC Use

Agent	Concentration (%)
Benzocaine	5-20
Benzyl alcohol	10-33
Butamben picrate	1
Dibucaine	0.25-1
Dimethisoquin HCl	0.3-0.5
Dyclonine HCl	0.5-1
Lidocaine	0.5-4
Lidocaine HCl	0.5-4
Pramoxine HCl	0.5-1
Tetracaine	1-2
Tetracaine HCl	1-2

some parts of the world since its introduction in the early 1950s. It was one of the first drugs to be shifted to the OTC market due to the extensive review initiated by FDA in the 1970s. Since the release of 0.5 percent nonprescription hydrocortisone products in 1980, hundreds of millions of people have applied it topically to self-treat itching and other inflammatory skin conditions. There is no indication that OTC products containing hydrocortisone are dangerous when instructions are followed. In fact, at the time of preparation of this article, efforts were underway to bring 1 percent hydrocortisone to the OTC market.

While hydrocortisone does not play an active role in healing sunburn, it may alleviate associated itching. Numerous studies have demonstrated hydrocortisone's effectiveness as an antipruritic, although the antipruritic action may not be felt for a day or two. A local anesthetic can be applied during this period.

Topical hydrocortisone has two fundamental actions. It constricts cutaneous blood vessels which prevents mobilization of white blood cells (polymorphonuclear leukocytes and monocytes) into the area. It also antagonizes the inflammatory response of mast cells and others that release mediators of inflammation. Therefore, itching is relieved.

Antimicrobials. Skin that is not broken has a minimal chance for becoming infected. Antimicrobials are therefore not necessary for mild burn injuries. For severe damage where the skin is broken, the chance for secondary infection is greater. Here, first aid antibiotic ointments may help guard against infection. If the affected area is extensive, physician supervision is necessary.

OTC Internal Analgesics. Aspirin and ibuprofen inhibit cyclooxygenase and reduce prostaglandin (PG) synthesis. Some experts recommend that 600 to 650 mg aspirin taken soon after sun exposure, and repeated every 2 hours for 6 doses, may prevent the delayed erythemic sunburn response. Other nonsteroidal anti-inflammatory drugs including ibuprofen theoretically have the same advantage. Acetaminophen does not exert the same action, but its analgesic action may also relieve sunburn discomfort.

Cold Water. Treating sunburns with

cold (but not ice-cold) water is a popular treatment. The temperature deep within skin structures increases following burning, causing continued extension of the local damage. Reducing the temperature with cold water lessens thermal damage due to coagulation of protein in surrounding areas. Cold water is also anesthetic. Because it is vasoconstrictive, it also suppresses local edema and potential reactive hyperemia (excessive edema).

Cold compresses may ease pain and minor symptoms from sunburn when applied as late as 45 minutes after injury. It may help reduce edema even when applied 4 hours after burn injury.

OTC Product Dosage Forms

Cream and ointment products should be applied in a thin layer and gently rubbed in. Creams are easier to apply than ointments, but are less protective against dryness. Ointments are superior for relieving dryness. Emulsion lotions are also effective in treating dryness.

Aerosol products have a distinct advantage in that they apply medication without the need to rub it in and increase discomfort. They also impart a welcome coolness to the skin when the propellants evaporate after application. Aerosol products should not be sprayed onto the face or near the eyes. If a consumer chooses to use a spray product on the face, medication can be applied to a hand, or on cloth or cotton, and then rubbed onto the face. Aerosol containers should also be kept out of direct sunlight, away from heat, and out of the reach of children.

Counseling Consumers on Sunburn and its Treatment

OTC sunburn remedies can be recommended with confidence. Most sunburns are minor and superficial. OTC products will not curtail the underlying burn process, or prevent blister formation, but they do offer relief of symptoms while the area heals.

When cold water therapy is recommended, the affected area should be immersed in cold water, or alternatively, water-soaked compresses may be applied. Burow's solution or other emollient or skin protectant products can be used if itching is intense. Fluid should be changed, or compresses re-soaked, as often as needed to keep the

area cool. Application should be maintained until the area is free from pain. The skin should then be gently patted, not rubbed, with a clean towel.

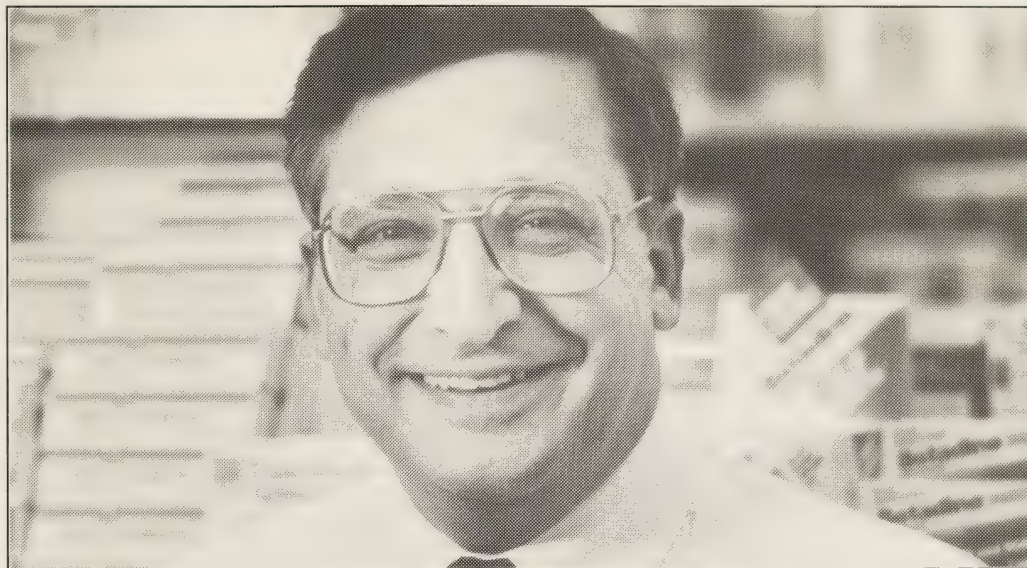
Minor sunburn must be distinguished from severe damage. Whenever there is doubt about extent of damage, the individual should be referred to a physician for assessment. It is recommended that the victim be referred when severe or extensive sunburn involves more than 10 percent of the body surface area of a child, or greater than 20% of an adult.

Applying first aid or palliative treatment to a severe burn at home may delay the time that the patient seeks a physician. Effective therapy for a severe sunburn can therefore be hindered and scarring worsened.

A person's history of sun exposure may not always correlate with the intensity of symptoms. Some people develop an exaggerated response after minimum exposure to the sun. The person may be taking a drug or using a cosmetic or other product on the skin that increases sensitivity to sunlight. Common photosensitizers in the U.S. include sulfonamide derivatives, (including thiazide diuretics and oral hypoglycemics), tetracycline and phenothiazine derivatives, cosmetics and beauty aids. Other causes of accentuated reactions include contact dermatitis and viral exanthems (eruptions), which may be worsened by sun exposure.

Needless to say, the best treatment for sunburn is to prevent it from happening. The use of sunscreens accomplishes this goal.

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Annual Report of the MPhA Committees

Third Party Committee
Chaired by: Phillip Marsiglia

Although the Third Party Committee has not had a formal meeting this year, it has been active and can claim a number of important accomplishments. The most time consuming and certainly the most fruitful endeavor has been the continued fostering of a close working relationship with the Maryland Medical Assistance Department. This relationship, which has its basis in the principle of give and take, has given us unprecedented access to the highest decision making level of the Department.

As a continuation of negotiations started last year, we finalized plans for a totally new reimbursement methodology. This formula allows the Department to achieve full compliance with the HCFA mandate to eliminate ALP as a measure of Estimated Acquisition Cost (EAC) and at the same time provides for a fair and equitable reimbursement for the States pharmacists. In addition to this accomplishment which is considered to be revenue neutral, we were able to convince the Department to reverse their decision to eliminate the 7 cent electronic tape submission incentive.

This reversal saved pharmacists \$70,000 in actual income, but more importantly, continued the principle that claims processing cost are the responsibility of processor and not the provider. We hope to use this principle to convince Blue Cross to reinstate their Tape Incentive or assume the cost of on-line adjudication. In addition, the committee worked with the Association leadership and the Department to devise a plan to save the Maryland Pharmacy Assistance Program from the "Budget Ax". That plan, which includes increased co-pays and restricts coverage to anti-infectives and maintenance drugs was devised by the Association and adopted virtually unchanged by the Department. Another achievement was the agreement of the Department to finally make available to the Association a list of price levels used in the generic IDC program. After reviewing the list and requesting changes from the Department, the list was formatted into a convenient document and distributed to all owner/manager members.

This year brought about the reestablishment of the Blue Cross Maryland Pharmacist liaison, a subcommittee of the Third Party committee. Two meetings were held with Prescription Health Services (PHS) to help ease the conversion of the Blue Cross Prescription Drug

Program to a on-line adjudication system. This committee will meet on a periodic basis in the future, when need dictates.

As a result of complaints from some members concerning late payments on Third Party Prescriptions, a three month study was conducted to determine if Third Party Administrators intentionally delay payments in order to increase their profit. Data from the survey is currently being tabulated and if the results support the complaints we have been receiving then appropriate inquiries will be made to those specific processors.

Professional Affairs Committee
Chaired by: Ilene Zuckerman

The Professional Affairs Committee is responsible for making recommendations related to issues that affect our professional practice (e.g., reimbursement for cognitive services, pharmacy technicians, physician dispensing, pharmacy practice standards). In addition, the Professional Affairs Committee is responsible for public affairs and peer review activities.

This year, the Committee commenced the task to develop standards of pharmacy practice in Maryland. These standards will include voluntary guidelines related to administrative issues, facilities, and equipment, prescription profiles and distribution, patient counseling and quality assurance. We expect this to be an ongoing process.

Upon recommendation of the Committee, MPhA purchased a portable exhibit that can be displayed at local and national meetings. The goal of this display is to enhance the public's awareness of the pharmacy profession and of the Maryland Pharmacists Association. The display is available free of charge for use by members; call the MPhA office for details.

In a continuing effort to promote the profession of pharmacy, the Committee is planning a program, "Ask Your Pharmacist", in October, 1991. This telephone call-in program will coincide with Maryland Pharmacy Day and the national Talk About Prescriptions Month in October.

The Peer Review Committee received several complaints from patients, mostly related to cost of prescriptions. However, there were several complaints related to "impolite pharmacists."

Nominating Committee
Chaired by: Howard Schiff, P.D.

The nominating committee gave its report at the 1991 Mid-year meeting in February. The following slate of candidates was presented:

President-elect: Murhl Flowers
Nicholas Lykos
Vice-President: Howard Schiff
Treasurer: Ronald Sanford
Trustee #1: Gerard Herpel
Ernest Testerman
Trustee #2: Ellen Yankellow
Kathrin Kucharski

Additional candidates for vice president and treasurer declined their nominations. An additional vice presidential candidate, Kathy Gauthier, was nominated from the floor at the House of Delegates. Elections were conducted by mail ballot and results were tallied by the Canvassing Committee as required by the bylaws.

The nominating Committee also nominated candidates for the two openings on the Board of Pharmacy. The nominees were:

Seat 1: Robert Kabik
Murhl Flowers
Wayne Dyke
Seat 2: Melvin Rubin
Milton Moskowitz
Stan Smith



Newly elected Vice Speaker of the House of Delegates Beverly Yachmetz and outgoing Speaker Murhl Flowers at the McKesson Banquet Reception.

Convention and Trips Committee
Chaired by: Elwin Alpern

Our trip to Puerto Vallarta, Mexico was well attended. We all shared breakfast each morning and continuing education daily. We received 8 hours of CE credit which was done at a leisurely pace and had the advantage of daily informal discussion periods. Our topic was most timely, Congestive Heart Failure and Cariogenic Shock. Eli Lilly and Company put the booklet together and our thanks go to them. Our association realized a profit of \$1,675.00 on this trip.

Our 1990 convention at the Sheraton attracted 42 paid exhibitors, with a gross of \$18,275.00. There were contributions of \$6,725.00 and a registration of \$18,972.00, net profit was \$8,113.46. Our Association for the year realized \$14,122.09 in revenues. This includes the mid-year meeting.

In January 1992 we will travel to 6 Islands via "Monarch of the Seas". Our price is very good and we will again offer CE for credits. We will advertise here at the convention as well as in the three other mailings. Space is limited to 50 cabins, so do not delay.

I would especially like to thank Jerry Freedenberg, Maribeth Porter and David Miller. Thank you for your continued support.



Delegate Jerry Fine congratulates Milton Moskowitz, 1991 winner of the Seidman Distinguished Achievement Award.

Publications Committee

Chaired by: Melvin Rubin, P.D.

The "Newsletter" Committee (of 1) was expanded during this Association year both in name and size, to include the responsibility for overseeing all Association publications, with Beverly Yachmetz, Kathy Parker, and Kim Moore added to the committee.

The main focus was on a long range plan to have the "Maryland Pharmacist" journal accepted as being more pertinent to the practices of the members. Although the journal is already recognized nationally as one of the better state magazines, past problems with timeliness has to be overcome. It is now back on schedule, to be in the hands of members by the end of the month of issue. To increase the usefulness, we are aiming toward "dedicated issues, which will have the largest portion of text relate to the same topics the same month of each year.

Many issues have already been dedicated, such as the Convention Issue, but starting in July 1991 we expect to have one or more topics annually in the respective months. Since some of the subject matter will be in conjunction with national topics such as Diabetes, Hypertension etc, we will highlight the topics the month prior to be sure the issue is in your hands in time to use for National months such as poison prevention.

The Newsletter has often been larger than the originally planned 4 pages, reflecting the expanded work

done by your Association. Dave Miller has done a great job of formatting the paper to enhance readability.

We have requested that each geographical and practice area appoint a representative responsible for sending information to be used in the newsletter and/or journal, and have so notified the organized groups we could identify. All members are encouraged to send information of interest including activities of groups or individuals, awards received by them, etc.

As in all MPhA undertakings we intend to cover the state. If you feel that your area is under represented in the newsletter, you only have to provide the information to your association office.

Past Presidents' Council

Chaired by: Elwin Alpern, P.D.

The Past President's Council was charged with selecting the scholarship and award winners for the 1991 year. This year we promote our scholarship program through the School of Pharmacy and received 24 applications.

PEP scholarships are awarded to students who can demonstrate a financial need during the summer months while they do Externships. The scholarships are in the amount of \$300.00 each. This year's recipients were Yunga Chang and Helen Rozies.

The Harry D. Kaufman Award is presented to a student who has demonstrated outstanding dedication and devotion to community service, while a student. The Award is in the amount of \$100.00. This year's selection for the Award was David Chen.

In selecting the Annual MPhA awards the past President's Council considered nominations from the membership.

The 1991 Bowl of Hygiea recipient is Irvin Fink of Randallstown.

The 1991 Distinguished Young Pharmacist Award recipient is Beverly Yachmetz of Damascus.

The Seidman Distinguished Achievement Award given to an MPhA member who has shown outstanding dedication to the profession is awarded to Milton Moskowitz of Silver Spring.



Outgoing Chairman of the Board Nat Futeral "welcomes" newly installed MPhA President Ilene Zuckerman.

Constitution and Bylaws Committee

Chaired by: Murhl Flowers

This has been a very difficult year for the Bylaws Committee. It was understood that major changes needed to be considered, especially since far reaching long term recommendations were expected to come out of the first Long Range Planning Meeting. This meeting was to be held in the fall so that recommendations could be made by ByLaws changes to be presented at our mid-year meeting.

The Long Range Planning Meeting could not be arranged until after the mid-year meeting. The By Laws Committee met and recommended changes to the House of Delegates in February. However, we did not submit them to the membership as we decided to wait until after the Long Range Meeting in the Spring.

Based on the feeling of the membership at the mid-year meeting, as demonstrated by "straw votes" taken, and the discussions at the Long Range Meeting, the By Laws Committee met in May to consider final recommendations to the membership.

We feel that these proposed changes reflect the wishes of the membership as well as incorporates the intent of the Long Range Planning Committee.

The major changes proposed are:

1. The addition of a Constitution. In the past, it was felt that the articles of incorporation we filed in 1989 was sufficient. This committee disagreed and added a Constitution.
2. The mission or objective of MPhA was consolidated and shortened by the Long Range Planning Committee.
3. The purposes of the association were changed to more correctly reflect the various aspects of pharmacy within Maryland.
4. Provides for a performance review of the Executive Director by the Executive Committee annually with the preparation of the yearly budget.
5. Increases the size of the Board of Trustees from 14 to 19.
6. Designates Board of Trustees seats to reflect pharmacy practice specialties; community Pharmacy; hospital, chain Pharmacy; independent owners; and, consultant/long term care.
7. Provides that the President-Elect be the chair of the Nominating Committee.
8. Charges the Nominating Committee to seek geographic diversity in making its nominations.
9. Provides for an audit committee and a semi-annual review of the records.
10. Provides the membership with three options from which to choose the composition of the House of Delegates:
 - A. Leave process as is: only voting delegates would be from affiliated and recognized organizations *plus* 20 Delegates-at-Large appointed by the Speaker.

B. Modified One Man/One Vote: Affiliated and recognized organizations would still appoint delegates *plus* any member in good standing would be a voting delegate.

C. One Man/One Vote: any member in good standing would be a voting delegate.

The feeling of the Bylaws Committee is that these proposed changes will serve the association well as we endeavor to make MPhA more reflective of the needs and to better the many varied practice settings in pharmacy throughout the State of Maryland.

My thanks to the committee members for their patience, concern and dedication and to all MPhA members who offered ideas and suggestions. It has been a pleasure to serve the Association as Chairman of the Bylaws Committee.



Wyeth Ayerst representative Ray Langston presents MPhA's 1991 Bowl of Hygiea Award to Irvin Fink of Randallstown. Dr. Fink's work with autistic children was featured in a recent issue of *Drug Topics*.

Long Range Planning Committee

Chaired by: Ken Whittemore, Jr.

"If a man knows not what harbor he seeks, any wind is the right wind." Seneca

From time to time, in every long-lived organization, it becomes necessary to take a close look at what the organization stands for, who its members are, where it plans to go and how it plans to get there. This is particularly true of an organization that functions in a turbulent environment. It is also true of an organization whose membership structure is changing over time. Since these two conditions clearly apply to our association, it is no wonder that the leadership realized last year that it was time to make a critical evaluation how the MPhA functions and where it is headed.

The first step in the evaluation process was the Long Range Planning Retreat which was held at the Bavarian Inn in Shepherdstown, WV the weekend of February 23 and 24, 1991. The meeting was attended by the officers, the trustees and the members of the Long Range Planning Committee. In addition, Dr. William Forgang, Dean of Graduate Studies at Mount Saint Mary's College in Emmitsburg, MD was present to act as the meeting facilitator.

The meeting began with an analysis of the Associa-

tion's strengths and weaknesses which was followed immediately by an analysis of the opportunities and threats which confront the Association. It was the consensus of the participants that the Association is a strong one that exists in a rather threatening environment. Upon deciding that the Association is basically a healthy one, the next step was to review the Association's mission and refine its mission statement, if necessary.

The purpose of a mission statement is to define the fundamental purpose of an organization. It is a clear, concise statement of what the organization is about. It serves to guide the organization's leadership as they decide on the strategy to be used to achieve the organization's goals. During the course of the retreat, the Association's Object, as stated in the current bylaws, was refined to the following Mission:

"The mission of the Maryland Pharmacists Association is to represent and serve pharmacists and to promote the highest standards of professional practice in Maryland."

In support of its mission, the Association has recognized several statements of purpose. These, too, were examined and refined as follows:

PURPOSES:

To promote the professional, financial and economic interests of its members.

To promote the common interest of those engaged in or associated with the practice of pharmacy in Maryland.

To promote and safeguard the public health and welfare of the people of Maryland.

To cooperate with other health care professionals and organizations.

To promote the proper use of prescription and non-prescription medications and health care devices.

Upon completing these two tasks, it was then appropriate to identify objectives that would further the Association's mission and serve its purposes.

Objectives are the goals which an organization attempts to achieve as it functions from day to day. Dur-



Outgoing President Mark Levi receives the Merck Sharp and Dohme Achievement Award from longtime MSD representative Frank Radigan.



Trustee Lynette Bradley, Vice-President Howard Schiff, President-elect Nick Lykos, Vice Speaker Beverly Yachmetz, Trustee Arnold Davidov, and Speaker Phil Marsiglia were installed at the Second House of Delegates Session on June 19, 1991.

ing the course of the retreat, the following objectives were identified:

LONG TERM OBJECTIVES:

- 1) Financial strength.
- 2) Membership growth.
- 3) Improved representation.
- 4) Greater participation.
- 5) Adopt/develop standards of practice and code of ethics.
- 6) Improved communications with members (especially policies.)
- 7) Improve continuing education programs.
- 8) Streamline board meetings and eliminate inefficiencies.
- 9) Improved needs awareness.
- 10) Increased public awareness.
- 11) Physical plant improvement.
- 12) Organization relations.
- 13) Increased participation in pharmacy education.
- 14) Improve professional status (e.g.—with third parties).

All of these objectives are important, but some are of greater significance than others. And, although an organization can and frequently does pursue more than one objective at a time, it often becomes necessary to break objectives down into more manageable pieces. Therefore, the participants determined that the following objectives should be given priority treatment over the next twelve months:

Annual Objectives

- 1) Increase financial reserves to have 1 year's operating budget by 1900. (Target date to be determined).
- 2) Membership growth by 00% per year. (Target percentage to be determined).
- 3) Increased growth/year of those attending MPhA meetings.
- 4) 1991—Define standards of practice in document. 1991—Distribute document for recognition by members.
- 5) Review and publicize MPhA policies.
- 6) Create annual policy manual.

- 7) More practice related continuing education, relatively less emphasis on science. Give broader geographic offerings.
- 8) Change agenda for meetings and teach parliamentary procedures.
- 9) Annual needs survey or focus groups.
- 10) Evaluate existing service (keep/eliminate).
- 11) Increase public awareness of pharmacy/pharmacist value through PSA campaign.
- 12) Improve lobbyist presence.
- 13) Maintain liaisons with third parties and develop information to be used for dialogues.

All in all, the Long Range Planning Retreat was a productive weekend. In spite of what was accomplished, however, there were some questions that lingered in the minds of many of the participants. The most prominent of these was the question: Just what do the members want or expect from their Association? Further, what are we or aren't we doing that prevents more pharmacists from joining the Association? To find the answers to these questions, it was decided that the Association staff and the Long Range Planning Committee would conduct a series of focus groups of many types of practitioners, both members and nonmembers alike. The input from these meetings will serve to guide the leadership in choosing the objectives that will be pursued in the future.

Another issue that became apparent during the retreat, which was later amplified by the facilitator's follow-up comments, was the dilemma of choosing a structure for the Association which would best provide for the representation of all of the various types of pharmacy practitioners while insuring that the Association remains intact. After two additional meetings, the Long Range Planning Committee decided that the first organizational change that should be made would be to alter the composition of the Board of Trustees as follows:

"The number of elected trustees should be increased from six to eleven and the seats should be designated seats, to be apportioned as follows:

- One hospital pharmacy seat
- Two community pharmacy employee seats
- One consultant/long term care seat
- One chain management seat
- One independent owner seat
- One pharmacy educator seat
- Four at large seats"

The committee also decided that each designated board member should act as a conduit for the views of his or her practice type. It was felt that this arrangement would serve as a good first step in the Association's movement toward a structure that would truly represent the interests of all practitioners.

Obviously, the Long Range Planning Committee does not have the authority to change the Association's structure at its whim. Therefore, all of the changes out-

lined above have been passed on to the Constitution and Bylaws committee as recommendations. These recommendations should now be working their way through the amendment process.

Long range planning is not an event—it is a continuing process. And, feedback is an important part of the process. As the Association proceeds with these changes and objectives, it will be very important for all members to let the leadership know whether or not progress is being made. Through such feedback, the Association will be able to fine tune its objectives and become far more important to the professional lives of all pharmacists practicing in Maryland.

The long range planning process could not have been initiated without the time and effort of many of the Association's membership. Speaking for myself and on behalf of the Association's membership, I extend thanks to the officers, the trustees and, in particular, the members of the Long Range Planning Committee: Ilene Zuckerman, Murhl Flowers, Mel Rubin, Richard Reitz, Al Schwartzman, Ron Sanford and Lee Ahlstrom. All those who were involved can rest assured that the process that was begun this year will set the Association on an appropriate course for the next five to ten years.

Drug Utilization Review Program

Chaired by: Richard Baylis, P.D.

I must say, after just completing my first year as DUR director for MPhA, this has been the most enjoyable and satisfying year I have ever experienced in my career.

We have just completed the second year of a three year contract with the state of Maryland's Medicaid Program. In the last year 27,144 profiles have been reviewed, resulting in 2,820 letters generated to both physician and pharmacist in each case.

Three special DUR studies have been conducted this past year. Two of the studies, Ceclor and Cipro were requested by the Medicaid Department, the third is an ongoing overview of problems in the nursing home population. A final report on the nursing home study will be presented at the annual meeting of ASCP in the fall.

The effects of our educational intervention efforts appear to be very successful. Several major drug manufacturers have expressed their concern about DUR activities targeting particular drugs produced.

A round table discussion on "The Proper Use of Benzodiazepines" was our first in a series of educational video tapes produced this past February. Participants included: physicians from Med Chi, pharmacists, nurses, and administrators of drug treatment centers. Future tapings will involve subjects such as "Sleep Disorders, Antibiotic Usage, and "Antipsychotic Drugs", etc.

The one year DUR pilot program run for Blue Cross/Blue Shield's state employees was completed as of February. DUR has submitted new bids and will be awaiting responses this fall and we are actively pursuing new contracts with several other health providers.

Maryland DUR will probably be the model for other states who must meet the requirements of the OBRA 1990 legislation. I have been actively involved with HCFA concerning this process. On July 10th, I will address a HCFA sponsored meeting in Baltimore on Medical Information Systems. I have also addressed the annual meeting of Med Chi in College Park to explain DUR to the physicians of Maryland and I am working with AMA to give a presentation to their members as well. In about a week, I will be addressing the Dutch Royal Society of Pharmacists in Utrecht, Holland and the Union National Pharmacie Francais in France.

One of our committee members and I are actively involved in a national coalition of DUR and Medicaid Directors, (ADURS). This person is one of three acting as a coordinator for the ADURS organization. ADURS, helps to assure our interests as the government proceeds with a national DUR program.

MAFDA Coupon Redemption Program

Chaired by: Mary Ann Frank

The Mid-Atlantic Food Dealer Association (MAFDA) coupon redemption program was started by the association in May 1985. The first year, more than 85 pharmacies joined the program.

Currently 116 stores are participating. Rebates of up to 3 cents per coupon plus a 30 day turn around make the program very attractive. From January 1990 to December 1990, the MAFDA program generated an income of \$8874.00 with a Store assessment of \$3500.00 leaving a net balance of \$5374.00.



Outgoing President Mark Levi, President Ilene Zuckerman, Trustee Lynette Bradley, and the two newest Trustees Gerry Herpel and Ellen Yankellow at the 109th Annual Awards Banquet.

The Pharmacists' Rehabilitation Committee

Chaired by: Harry Finke, P.D.

During the year the Committee saw 6 pharmacists complete their treatment contract. Eleven new cases were added to the caseload bringing the current total to 28 active cases. Of these, 15 are referred by the Maryland State Board of Pharmacy.

The Committee is comprised of 11 active members of the Maryland Pharmacists Association. Members of the Committee receive special training through participation in the Utah Summer Institute on Alcoholism and

Other Drug Dependencies. This week long residential program is highly recommended for anyone interested in the field of addictions treatment. Over the past several years the American Pharmaceutical Association has promoted the Utah program as the single most important training throughout the country. The Committee has sponsored this training or each of its members and in addition has been instrumental in sending students from the Pharmacy School as well. During this year three students received training at this program.

The training of students is an investment in the future of the Committee. Students are drafted onto the Committee following their graduation from the school if they remain in the State of Maryland to practice. Additionally the students are part of a cooperative program with the Pharmacy School. The school has established a student peer program to provide assistance to other students having problems related to alcohol or drugs. This program is a joint effort of the School and the Committee.

Funding for the Committee is provided through the generosity of the MPhA membership and through additional donations from the members of the MSHP. Following the death of his son, Milton Moskowitz this year established the Fred Moskowitz Fund in his honor. Donations to the fund will be set aside to support the important work of the Committee. The following is a brief accounting of the Committee's revenues and expenses.

Fund Balance 1/1/90	\$5439.97
Income	\$6720.00
Expenses	\$4797.29
Fund Balance 12/31/91	\$7362.68

The Committee continues its efforts to increase its visibility. Members participated in a forum at the Johns Hopkins Hospital and have taken advantage of other opportunities to make the program known in the pharmacy community. Students in the Pharmacy School are taught about the role and function of the Committee as part of the core curriculum of the School. A continuing education program is planned for the Fall of the current year.

The Committee enjoys an excellent working relationship with the State Board of Pharmacy. Our program has been a model for pharmacy associations in other states.

Oversight Committee

Chaired by: Nicholas Lykos

1. Reviewed MPhA DUR programs with the State and Blue Cross and Blue Shield. Found programs satisfactory and staff competent and knowledgeable.
2. CE Program & CECC—Reviewed our programs and interaction with CECC. Recommended that the association should be properly compensated, therefore, an agreement should be made with responsible parties.
3. Physical Plant Inspection

A. Exterior—Building, roof, and shutters are all in good shape. Scattered trash in grates, etc. Recommended that the exterior sign should be repainted and the replacement of "Pharmaceutical" with "Pharmacists" Association.

B. Interior—The B. Olive Cole Museum is in good shape. George Garmer, a 1991 graduate from the University of Maryland School of Pharmacy, has been named curator of the museum.

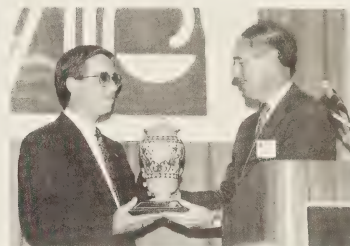
Library—Too crowded with office furniture.

Executive Director Office—Paneling on the north wall.

Entrance, foyer, office area—Too cluttered. Recommended extensive new floor plan.

Stairway—No ceiling fixture or curtain on window.

Basement—Needs extensive house cleaning and overhauling for future use.



Outgoing President Mark Levi receives a reproduction of an antique apothecary vase in recognition of his service to MPhA over the past year from Tom Burkhardt of Bristol Myers/Squibb.

Legislative Committee

Chaired by: Nicholas Lykos

The Committee was charged by the Board of Trustees to enact HB 112, 118, 119 and monitor TriPLICATE Prescription SB 193 and monitor any and all bills that affect the practice of pharmacy. The Committee worked diligently on more than 40 different bills that impacted on pharmacy. [For a complete analysis of MPhA legislative activity this past year, see the June 1991 issue of *The Maryland Pharmacist*.]

HB 112—Declares a physician to be liable in hiring a pharmacist in the traditional setting. Presently pharmacists could not work for a physician. Bill enacted.

HB 118—Authorized pharmacists in a declared federal or state emergency to refill a prescription up to a maximum of seven days supply of medication if unable to reach prescriber. Bill enacted.

HB 119—Removes the requirement for the USP/NF in all pharmacies. Allows other text to be substituted in library. Bill enacted.

SB 193—The ubiquitous triplicate prescription bill was back again. Was down graded to serialized and killed in the Senate. A comment on this bill—it will be back again next year and a concerted effort should be

made to get it resolved in a workable fashion to protect the public within good pharmacy guidelines.

HB 173—Placing anabolic steroids into Class III—a copy of the federal legislation. We originally objected to proposed bill until six amendments were made to make it workable. Bill enacted.

HB 255—Would allow pharmacy and other Boards to appeal an adverse court decision sponsored by the



Executive Director Dave Miller, Maribeth Porter and DUR Director Richard Baylis are all smiles at the success of this year's convention. We hope to see everyone at next year's meeting.

administration. MPhA was the only body to testify against this bill. Bill killed in House committee.

HB 409—Another administration bill that would allow the Governor to broaden his choice for appointees; also procedures to remove members. MPhA was the only body to object in the House. Bill killed in Senate committee.

HB 416, HB 618, HB 1263, SB 317, SB 633—All these bills were enacted with MPhA's support. They all dealt with prompt payment and the charging of interest on delinquent payments.

HB 783—Department's bill on Maryland Pharmacy Assistance Program increasing copay to \$5.00 and limiting coverage to maintenance and anti-infective medicine as defined by the Department and MPhA. Bill enacted with MPhA support.

HB 1191—Proposed bill to allow freedom of choice to join a HMO in providing pharmaceutical services. Delegate Weir approached MPhA and stated his plan to introduce this bill. Bill was recommended to summer study by both the Environmental and Insurance Committees—at which both lobbyist Robin Shaivitz and David Miller will testify.

SB 271—Allows Medicaid recipients the right to change MAC providers within 30 days. MPhA supported. It passed the Senate but was killed in the House. There were numerous other bills that your committee actually worked on regarding shoplifting, hearing aid batteries, monitoring of AIDS, etc.

Our 4th Annual Legislative Breakfast was held on February 27, 1991 at the Maryland Inn in Annapolis. The Governor again addressed the attendees. Session was from 7:00 am to 9:00 am and fairly well attended by Senators and Delegates. Pharmacists and supportive organization members were also well represented. Later

that morning, committee members along with other volunteer MPhA pharmacists distributed our "survival bags" to all delegates and senators at their offices and the executive office building. Bags were well received and appreciated. Next year we plan the continuation of the above with possible two "power lunches" with key committee members of the General Assembly.

The ability of MPhA to interact with all facets of our political sphere were well received and fruitful. MPhA met in the fall with Delegate Donald Elliott and Delegate Bennett Bozman and reviewed our legislative desires and plans. We had our annual meeting with the Maryland Pharmacy Chain Committee to discuss our goals. This year for the first time, we had a similar meeting with Maryland Pharmacy Government Affairs Committee which was very beneficial to both parties and we will continue the meeting annually.

MPhA interacted with the board of Pharmacy on legislative affairs synergistically. MPhA also interacted with the Maryland Chirurgical Society, the Maryland Chamber of Commerce, the Maryland Retail Association, the Baltimore County Chamber of Commerce, Blue Cross and Blue Shield of Maryland, the Department of Health and Mental Hygiene and other various health professions.

Unfortunately, our interaction with national legislation and pharmacy practice we found that MPhA was well ahead of APhA and NARD is providing service to the membership. The responsibility of this MPhA organization is to prepare our pharmacist for the enactment of Anabolic Steroid Class III and the HCFA list of authorized and unauthorized manufacturers for Medicaid prescriptions.

Our internal process of tracking bills imposed this year and we feel we have developed a format that keeps the committee and membership apprised. We look forward to implementing a letter tracking system for our pharmacist to respond to the association's request for a dialogue with elected representatives.

In summary, I would like to thank the members of our committee, our dedicated and hard working lobbyist, Robin Shaivitz, and our capable executive director David G. Miller and his staff. It has been a pleasure to serve the organization.

Membership Committee

Chaired by: Alfred Schwartzman

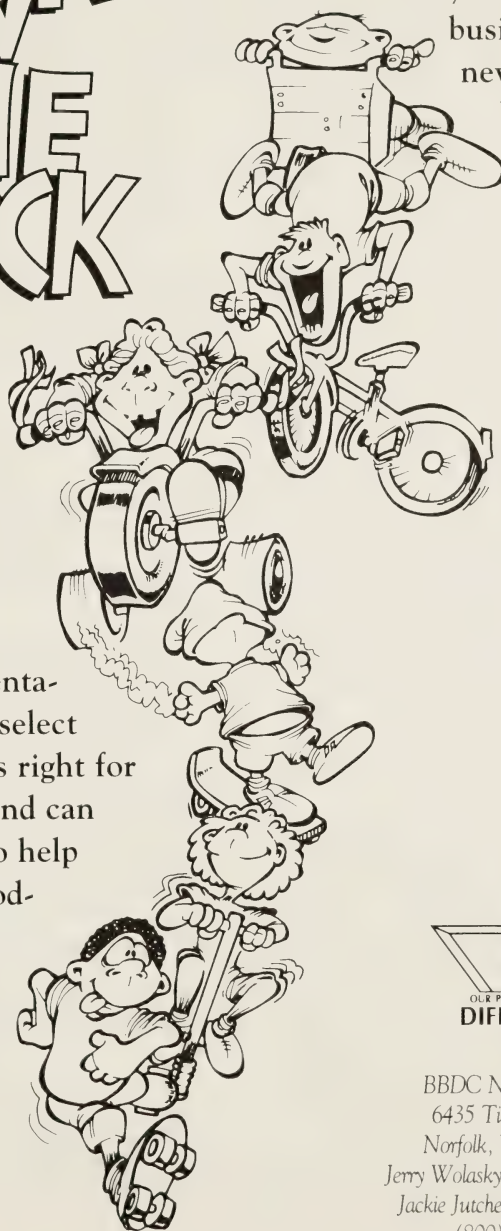
The Membership Committee was quite active this year. In April we held our first membership telethon from which 38 new members were recruited into MPhA. Also in April, every pharmacist in the state—both member and non-member—received a copy of the MPhA monthly newsletter with an application form. In July, we are planning a repeat of 1989's successful ½ off dues promotion.

As of this meeting, MPhA membership stands at 1,030. This is only 100 less than our highest membership year (1989) in the past decade. 1991 also is our highest student member year ever—217!

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1991 Resolutions of the House of Delegates

Resolution #1: Third Class of Drugs

Whereas, the Maryland Pharmacists Association recognizes that in the near future, many prescription drugs will obtain over-the-counter status even though they may have potentially dangerous side effects or serious drug interactions; and,

Whereas, in order to better serve and protect the general public these medications should be sold only in outlets which have a pharmacist available for consultation;

Therefore, be it resolved that the Maryland Pharmacists Association seek legislation to mandate a phase-in "Sale by Pharmacy Only" period for all prescription legend medications which change to OTC status.

Adopted: June 19, 1991

Resolution #2: Expansion of Continuing Education Programs

Whereas, the expansion of the current live continuing education programs offered by the Maryland Pharmacists Association would allow for greater access to the Association by its members as well as attracting new members;

Therefore, be it resolved that the number of live continuing education programs offered by the Maryland Pharmacists Association should be increased from two to six per year; and,

Be it further resolved that each program would be held in a different geographic area of the state and be non-repetitive; and,

Be it further resolved that the programs would be open to all pharmacists statewide and, whenever possible, be held jointly with local pharmacy associations; and,

Be it further resolved that at each program a segment would be included that informed all pharmacists in attendance the accomplishments of the Association and the goals towards which it is working.

Adopted as amended: June 19, 1991

Resolution #3: Timely Notice

Whereas, more and more third-parties are failing to provide timely notice to pharmacies when prescription benefit plans undergo changes in product coverage, reimbursement determination, and other areas that impact on the service pharmacists provide to the third-parties subscribers; and,

Whereas, the recent drastic change in covered drugs by the Maryland Medicaid Program provided pharma-

cists with less than a week to make significant computer changes and resulted in lost revenues to pharmacists;

Therefore, be it resolved that the Maryland Pharmacists Association seek by regulation and legislation a requirement that all insurers, HMOs, third-party administrators, Medicaid and any other program that provides pharmaceutical benefits must notify that program's participating pharmacies of changes to the program's rules and requirements at least 30 business days in advance of the proposed change; and,

Be it further resolved that this legislation and regulation require that if the program fails to provide such notice, any claim submitted from the date of notice until 30 business days after the notice must be honored and paid in full under the program's guidelines in place before the date of notice.

Adopted: June 19, 1991

Resolution #4: Single Serialized Prescriptions Drugs

Whereas, the Governor's Prescription Drug Commission has met and recommended that the State of Maryland institute a system of single serialized prescriptions for all Schedule II drugs; and,

Whereas, this system will require all pharmacies to provide, on a monthly basis and on a medium approved by the Department, a report of all dispensed Schedule II drugs;

Therefore, be it resolved that the Maryland Pharmacists Association support the concept of single serialized prescriptions and the submission of the data from these prescriptions; and,

Be it further resolved, that our support of this system is contingent on the provision of monies to enable pharmacies to adapt their computer systems to this new requirement as well as the provision that cost of data submission will be borne by the Department; and,

Be it further resolved that our support of this system is also contingent on the requirement that the Department's data collection system must comply with nationally recognized computer standards such as those developed by NCPDP or ASAP.

Defeated: June 19, 1991

Resolution #5: Standards of Practice

Whereas, there has been marked interest on a national, state, and local level through regulation and legislation to further inhibit the pharmacists' ability to practice their profession in the manner in which they were educated; and,

Whereas, it is imperative that organized pharmacy take responsibility for deciding what is and is not appropriate pharmacy practice;

Therefore, be it resolved that the Maryland Pharmacists Association define the standards of practice of pharmacy in the state of Maryland; and,

Be it further resolved, that the Maryland Pharmacists Association work with the Maryland Society of Hospital Pharmacists and other pharmacy groups so that the standards of practice accurately reflect pharmacy's varied practice areas; and,

Be it further resolved, that the Maryland Pharmacists Association make a standards of practice document available to every pharmacist in the state.

Adopted: June 19, 1991

Resolution #6: Mandatory Patient Counseling

Whereas, pharmacists have the professional education, skills, and expertise to conduct their practice and care for their patients as they see fit; and,

Whereas, recent attempts to mandate patient counseling dictating to pharmacists through regulation and legislation represent a gross incursion on every pharmacist's professional decision-making processes; and,

Whereas the Federal Omnibus Budget Reconciliation Act (OBRA) of 1990 requires patient counseling for Medicaid patients in order for each state's Medicaid program to continue to receive federal matching funds; and,

Whereas the standards of practice currently being developed by the Maryland Pharmacists Association will delineate standards based upon the pharmacist's professional judgement for counseling of both Medicaid and non-Medicaid patients.

Therefore, be it resolved that the Maryland Pharmacists Association oppose any regulatory or legislative activity that mandates patient counseling by pharmacists; and,

Be it further resolved that the Maryland Pharmacists Association pursue the State's recognition of the standards of practice, developed by the Association, as sufficient to meet the requirements of the Federal Omnibus Budget Reconciliation Act (OBRA) of 1990.

Adopted: June 19, 1991

Resolution #7: Commendations of Servicemen

Whereas, pharmacists risked their lives serving their country in the Persian Gulf Conflict; and,

Whereas pharmacists fulfilled their professional obligations in the Medical care of United States Forces serving in the Persian Gulf; and,

Whereas, pharmacists helped in the success of Operation Desert Storm,

Therefore be it resolved that the Maryland Pharmacists Association honor and commend the pharmacists that served in the Persian Gulf in 1990 and 1991.

Adopted: June 19, 1991

Resolution #8: Smoke-free Pharmacies

Whereas smoking has been identified as the greatest preventable cause of premature death and disability from cardiovascular disease and cancer; and,

Whereas second-hand smoke (ie. smoke breathed in by non-smokers) has been similarly identified as a major risk factor for cancer, stroke, and heart disease; and,

Whereas the State of Maryland has the highest cancer death rate in the country; and,

Whereas all State of Maryland offices, large retail stores, and most health facilities have adopted non-smoking policies to assure a smoke-free environment; and,

Whereas the pharmacy practice site is a health facility that is frequented by many persons for whom tobacco smoke is a definite hazard to their health and well-being.

Therefore be it resolved that the Maryland Pharmacists Association strongly recommend and encourage that all pharmacies be smoke-free and that implementation of this policy be accompanied with appropriate public education programs, including the conspicuous posting of signs.

Adopted: June 19, 1991

Resolution #9: Single-level Degree Programs

Whereas, the SRI International Study entitled "An Assessment of Future Educational Needs for Community Pharmacists," concludes that:

the educational requirements for a generalist pharmacist with the expanded role of "drug use counselor" can be met by the current 5-year program, with some modification in content; and,

Whereas, NARD, the organization representing retail pharmacy, surveyed its members and found that 62.4% believe that the period of time required to complete the entry level professional degree should be 5-years; and,

Whereas, the American College of Clinical Pharmacy surveyed its membership of over 1,800 actively practicing clinical pharmacists in January 1991 and reaffirmed their position that pharmacists educated at both the baccalaureate and doctoral levels are needed to adequately meet the full spectrum of society's drug therapy need and that societal expectations do not justify training all pharmacists at the Doctor of Pharmacy level; and,

Whereas, only universities can grandfather doctoral degrees, and universities traditionally have been hesitant to grandfather a doctoral degree to students with a 5-year professional degree; and,

Whereas, the Gallop Organization surveyed 1,002 faculty members from the schools and colleges of pharmacy and found 60% of faculty members feel that the required length of study to complete an entry-level degree for community pharmacy practice should be

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5-years and 67% of faculty members oppose conversion from a B.S. program to an all Pharm.D. program if it had to be made with existing facilities and financial resources; and,

Whereas, the National Association of Boards of Pharmacy reported that Maryland led the nation for incoming licensure transfers in 1990 with more than 68% of Maryland's licensure transfer activity involving pharmacists moving *into* the state indicating that more pharmacists are licensed through reciprocity than are licensed by examinations; and,

Whereas, the University of Maryland is experiencing serious budget cuts from the state and efforts to lengthen a pharmacy program would be costly to this school; and,

Whereas, an alternative to absorbing these costs would be to cut class size, causing the existing pharmacist shortage to grow to a more severe level nationwide and in Maryland, specifically, since there is only one pharmacy in the state;

Be it resolved that the Maryland Pharmacists Association recognizes and upholds the need to maintain a multiple-degree structure to adequately train pharmacists now and in the future to meet the societal expectations of those patients we serve; and,

Be it further resolved that the Maryland Pharmacists Association opposes the move to a single entry-level Pharm.D. program, not only as the University of Maryland School of Pharmacy has proposed, but also as is delineated in the American Council of Pharmaceutical Education's Declaration of Intent.

Tabled: June 19, 1991

Resolution #10: Affiliation with ASCP

Whereas, the Maryland Pharmacists Association is currently affiliated with two national pharmacist organizations—the American Pharmaceutical Association and the NARD; and,

Whereas, an increasing number of Maryland pharmacists and members of MPhA are becoming or are currently involved in providing consultant pharmacist services to patients; and,

Whereas, the American Society of Consultant Pharmacists is the national organization representing practitioners in this area of pharmacy practice;

Therefore, be it resolved that the Maryland Pharmacists Association pursue "Affiliated Organization" status with the American Society of Consultant Pharmacists.

Adopted: June 19, 1991

Resolution #11: Preprinted Prescription Pads

Whereas, preprinted prescription pads are already illegal for controlled substances; and,

Whereas, preprinted prescription pads are nothing more than a form of advertising from manufacturers; and,

Whereas, preprinted prescription pads may sway a

physician from using a less expensive therapeutic alternative;

Therefore, be it resolved that the Maryland Pharmacists Association seek legislation that would *prohibit the use of prescription pads by prescribers that include either the advertising of a manufacturer of pharmaceuticals or the name of a drug product on the prescription pad or included within the packet of pads.*

Adopted as amended: June 19, 1991

Resolution #12: Recordkeeping for Needles

Whereas, AIDS is a major epidemic concern and the use of old syringes and needles are a contributing factor to its spread; and,

Whereas, there is distribution of free needles and syringes;

Therefore, be it resolved that the Maryland laws relating to the sale of syringes and needles be modified to permit sale without the necessary requirements for identification and record keeping.

Defeated: June 19, 1991

Resolution #13: Practice Standards

Whereas, the pharmacy association is presently re-evaluating and updating the practice of pharmacy standards;

Therefore, be it resolved that they examine the ratio of large volume prescription stores that employ an insufficient number of pharmacists as related to the number of auxiliary personnel not only at the high end but also at the low end; and,

Be it further resolved that they examine the hours required on the shift (sometimes 12 to 14 hours) and the turn around time.

Referred to Committee: June 19, 1991

Resolution #14: Drug Sampling to Physicians

Whereas, the current system of drug sampling still has the potential for diversion, despite current legislation; and,

Whereas, representatives may leave large quantities of samples even when they feel there is a great potential for misuse in order to remain economically competitive; and,

Whereas, uncertain storage and transport procedures, exposure to excessive heat or cold, now exist for physicians to receive samples. This may lead to adulteration and thus ineffective medication being given to the patient; and,

Whereas, the unregulated and uncontrolled storage of samples in physicians' offices is an open invitation for unauthorized use or abuse of drugs;

Therefore, be it resolved that the Maryland Pharmacists Association seek legislation to ban physician drug sampling in this state; and

Be it further resolved, that a system of sampling similar to "Pharmascripts" be instituted.

Tabled: June 19, 1991

Resolution #15: CE Program Requirements

Whereas, Maryland has adopted mandatory continuing education for pharmacists to ensure that pharmacists are prepared and educated to best serve the medical needs of the citizens of Maryland; and,

Whereas, the updating of pharmacists is a continuing process, one that never ceases; and,

Whereas, there is currently an exemption for newly licensed pharmacists whereby they are not required to earn continuing education credits until after their first license renewal date;

Therefore, be it resolved that the Maryland Pharmacists Association by legislation action change the mandatory continuing education requirements to eliminate this exemption so that all pharmacists must earn continuing education credits immediately upon being licensed.

Adopted: June 19, 1991

Resolution #16: Calculators with the NABPLEX

Whereas, the House of Delegates in June 1986 adopted a resolution supporting the use of calculators on the NABPLEX and requesting that the Maryland State Board of Pharmacy support a national initiative for that purpose; and,

Whereas, the National Association of Boards of Pharmacy defeated the resolution and stated that some students would use expensive or programmable calculators that would give them an unfair advantage over other test takers;

Therefore, be it resolved that the Maryland Pharmacists Association request the Board of Pharmacy to propose this issue to NABP again; and,

Be it further resolved that since NABPLEX charges nearly \$250 to take the exam, that the NABP shall supply a simple calculator to be utilized by the examinees.

Adopted as amended: June 19, 1991

Resolution #17: Time for Business

Whereas, the business of the Association has become more complex and varied; and,

Whereas, the time allocated to conduct the business of the Association at the Annual Convention has been cut back in recent years; and,

Whereas, there is a need for adequate time for thorough discussion and debate of these issues;

Therefore, be it resolved that the Executive Director shall schedule a minimum of five (5) hours for meetings of the House of Delegates on two separate days at the Convention; and,

Be it further resolved that the time scheduled shall be at the hours most appropriate for the highest anticipated attendance.

Defeated: June 19, 1991

Patient Counseling— New Emphasis in Pharmacy Practice

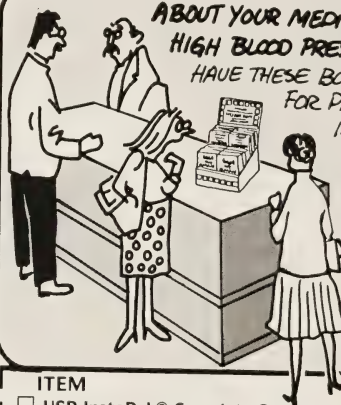
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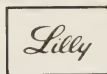
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Commitment to Excellence

Commentary

Dickinson's Pharmacy

Jim Dickinson

Goodby, 30-day fills. Most readers of this column doubtless regard Medicine Shoppes as competition, if not even "unfair" competition.

But put past ideas aside for a few moments to consider an innovation this franchisor is experimenting with, and what it could mean to pharmacy overall—independents banding together for the purpose of active soliciting third-party business on the basis of 90-day fills.

This is a good step beyond reluctantly accepting such a contract when it's jammed down your throat!

And at first blush, there's the natural reaction that such marketing only hastens the profession's own doom by playing the mail-order companies' own game on their own turf without their drug cost advantages (discriminatory pricing purchases).

But listen to Gary Levine, vice president of Medicine Shoppe International's managed care department. "The last thing we need is more low-margin business," he told us recently, explaining his 90-day fill experiment.

Levine is designing AWP-based prescription management programs for self-insured plans, using sophisticated data reporting features to help control waste and improve care—in short, promoting pharmacy *service* over price alone.

To build networks for specific contract negotiations, Levine says Medicine Shoppe often invites non-franchise pharmacies to participate along with franchised Medicine Shoppes.

For credible bids against mail-order plans, he has even developed a formulary of maintenance drugs for contracts requiring a 90-day supply.

"We have accessed a substantial amount of business this way,"

Levine told us. Until now, that business has been with HMOs and third-party administrators (TPAs), but several currently pending bids are with self-funded employers—which Levine says are more receptive to the concept of design savings than are HMOs and TPAs.

One of these, the Altoona (PA) school district, is considering four other bids—one from a local wholesaler-funded PSAO (Valu-Script), one from the current contractor (Blue Cross/Blue Shield), and one from a mail-order program (FlexRx); the fourth was not known when this column was written. The school district expects to announce its choice 7/1 or 9/1.

Levine told us that regardless of the outcome of its pending bid in Altoona, his company will use that proposal as a model for Medicine Shoppe networks with other employer groups across the country. "We go in as a consultant to the plan, and not as a pharmacy *per se* or a TPA," Levine said.

"We design something they want, rather than a plan with incentives to steer beneficiaries into something they don't want.

"Our aim is to preserve business for our franchisees, so it doesn't go to mail-order or some closed panel like a chain or PPO network. Our objective is to create an environment where you can put a well-conceived, well-designed, well-administered, well-managed program together and show the client that there's more to managing the drug benefit than the contract rate. I've sat on the other side where I was the TPA to the managed health care program, and seen the duplication of therapy, the inappropriate therapy—and I couldn't see what was done about it."

What Medicine Shoppe does about it, Levine says, is "much more intensive a selling process than simply saying, 'We have a network and a discount rate.'"

Unlike the mail-order operator who simply provides a list of "we can do" features, Medicine Shoppe explains the cause-and-effect relationships involved (patient, prescriber, pharmacist, program) so that plan payors *understand* where the efficiencies are found.

"I feel it's essential for independent pharmacy—not just our stores—to have access to such a program, otherwise we're going to be at the mercy of everybody who comes up with a new approach to cutting pharmacy reimbursements and even bypassing pharmacy altogether as a valuable member of the team."

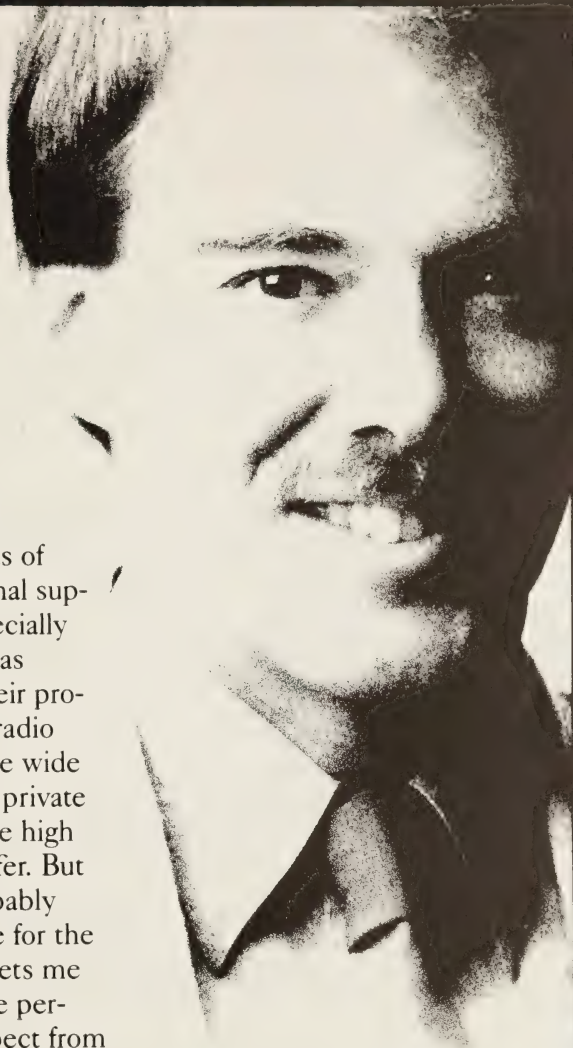
For this reason, Medicine Shoppe will often treat non-franchise members of its networks as equals, even to the extent—as in Altoona—of not charging participation fees. Further, administrative costs are charged to plans, not stores.

It may be too much like playing the mail-order game for some pharmacists.

But in the realities of the modern managed-care world that has been shaped—whether we like it or not—by the predatory practices of mail-order companies, it responds aggressively to 90-day fill policies.

In maintenance therapy, the 30-day fill is going the way of the dinosaur.

This feature is presented on a grant from "Dickinson's Pharmacy—The Independent Voice," a professionally stimulating 8-page monthly newsletter available from Ferdic, Inc., P.O. Box 848, Morgantown, WV 26507-0848 at an annual subscription fee of \$45.



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Scott Rickards

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No. 18

Children's Aspirin—Not Just for Kids Anymore

Two New Jersey pharmacists recently submitted reports through the USP Drug Product Problem Reporting Program (DPPR) questioning the packaging of 81-mg Aspirin Tablets in maximum quantities of 36 tablets per bottle. The pharmacists pointed out that adults, not children, are a big population using this product. The reporters indicated that the 81-mg Aspirin is now available in unflavored tablets, used by adults for preventative cardiac therapy and some of the currently marketed products are labeled as "adult chewable aspirin".

USP REVIEW

As pharmacists are aware, manufacturers are required to package drug products according to USP specifications. The current USP monograph for Aspirin Tablets states that tablets of 81-mg strength or less must be packaged in quantities no greater than 36. The history of this standard, adopted by USP in 1970, arose from the occurrence of accidental Aspirin poisonings in children. The limit on the number of tablets per container for the "pediatric strength" of Aspirin was designed to help prevent these poisonings.

Prior to the adoption of the standard in 1970, both "pediatric" as well as "adult strength" Aspirin Tablets were available in flavored dosage forms. At the time, it seemed to be common practice for consumers to divide the "adult strength" tablets into smaller doses to administer to children. However, if the calculation of the proper pediatric dose was not correct, or if the "adult strength" tablet was taken in error, overdoses would occur. The USP standard now states that Aspirin Tablets stronger than 81-mg are not to contain any sweeteners or flavorings. It was hoped that by eliminating sweeteners and flavorings in the "adult strength" Aspirin Tablets, consumers would be less likely to administer them to children.

The packaging and flavoring of aspirin tablets are addressed by a Food and Drug Administration (FDA) regulation as well. Under 21 CFR 201.314, regarding the labeling of drug preparations containing salicylates, it is recommended that aspirin tablets made especially for pediatric use be produced only in 81-mg strength and that retail packages of this strength contain no more than 36 tablets per bottle. It is also recommended that 325-mg aspirin or any other "adult aspirin tablets" not contain flavorings. These recommendations were published prior to the adoption of the Poison Prevention Packaging Act of 1970.

The Poison Prevention Packaging Act and its regulations, administered and enforced by the Consumer Product Safety Commission, designates products for which special packaging is required in order to protect children from serious personal injury or illness in the handling, use, or ingestion of the substances contained therein. The special packaging, required by the Act, is more commonly known as child-resistant packaging. Substances named in the Act include drug products as well as household products.

As it specifically relates to aspirin, the Poison Prevention Packaging Act states that, with the exception of some effervescent tablets containing aspirin and some powdered dosage forms containing aspirin, all aspirin-containing products intended for human oral use must be in special child-resistant packaging so as to prevent poisonings, regardless of the number of tablets in the container. This applies to all aspirin tablets, regardless of flavoring or strength.

When the USP packaging quantity limits for Aspirin Tablets became official, children were the primary population using the 81-mg size Aspirin Tablets for pain relief and fever reduction. The intended uses of small doses of Aspirin today have expanded markedly. *USP DI* Volume I lists several conditions in which prophylactic Aspirin therapy is an accepted indication due to the inhibiting effect of Aspirin on platelet aggregation. The comments received from the New Jersey pharmacists have been forwarded to the USP Drug Standards Division. The USP Committee of Revision is considering the possibility of changing the Packaging requirement to: Preserve flavored or sweetened Tablets of 81-mg size or smaller in containers holding not more than 36 Tablets each. If adopted, this change would permit larger quantities of the unsweetened Tablets to be packaged.

To report drug product problems or for further information, call the USP DPPR Program at 1-800-638-6725.



President Ilene Zuckerman shows off her NARD Pharmacy Leadership Award and her new MPhA President's Gavel. Ilene promises that the gavel will be put to good use in keeping the Association on track through the next year.



1991 Recipient of the Seidman Distinguished Achievement Award for outstanding career contributions to the pharmacy profession, Milton Moskowitz's report from the Board of Pharmacy will be featured in next month's issue of *The Maryland Pharmacist*.



Ciba-Geigy Pharmaceuticals has introduced Lotensin 10mg (benazepril) a new ACE inhibitor. The recommended initial dose is 10mg once daily. The usual maintenance dose is 20-40mg per day as a single dose or in two equally divided doses.



Clean Sights from Blairex Labs brings new convenience to pre-moistened tissues with a cleaning solvent that dries instantly and is safe for everything from computer screens to eyewear.

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Continuing Education

Continuing Education Quiz

The Maryland Pharmacist

AUGUST 1991

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by December 31, 1991. A continuing education certificate for one contact credit will be mailed to you within 30 days. Please type or print clearly.

Name _____

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Is this program used to meet your mandatory CE? ☐ Yes ☐ No

Did this article achieve its stated objectives? ☐ Yes ☐ No

How long did it take you to complete the program? _____ minutes

Sunburned Skin

1. Which of the following burns causes the most damage to the skin?
 - a. First degree
 - b. Second degree
 - c. Third degree
2. Which of the following is proven safe and effective for self-medication of pain of sunburn?
 - a. Camphor
 - b. Diphenhydramine
 - c. Menthol
 - d. Pramoxine
3. Which of the following is most responsible for tanning of skin?
 - a. UV-A
 - b. UV-B
 - c. UV-C
4. All of the following statements about prostaglandins (PG) are true EXCEPT:
 - a. PG levels in the skin decrease after ultraviolet irradiation.
 - b. sunburn blister fluids contain significantly elevated PG concentrations.
 - c. blocking PG synthesis attenuates the sunburn reaction.
 - d. injecting PG into the skin causes erythema.
5. All of the following are safe and effective local anesthetics for OTC use EXCEPT:
 - a. dibucaine.
 - b. lidocaine.
 - c. procaine.
 - d. tetracaine.
6. When recommending OTC sunburn remedies, all of the following points should be conveyed to consumers EXCEPT:
 - a. most sunburns are minor and superficial.
 - b. OTC products curtail the burn process and prevent blistering.
 - c. adults with extensive sunburn over 20% of their body should contact a physician.
 - d. OTC products relieve sunburn symptoms while the affected area heals.
7. All of the following local anesthetics are available OTC in an aerosol dosage form EXCEPT:
 - a. Americaine.
 - b. Dermoplast.
 - c. Solarcaine.
 - d. Xylocaine.
8. The delayed erythema response to sunburn is most likely due to:
 - a. histamine.
 - b. prostaglandins.
 - c. serotonin.
 - d. acetylcholine.
9. The pigment formed in specialized cells in the basal layer of skin responsive to ultraviolet radiation is:
 - a. collagen.
 - b. erythrin.
 - c. coagulin.
 - d. melanin.
10. Which of the following OTC skin protectants provides both moisturizing and lubricating effects?
 - a. Allantoin
 - b. Dimethicone
 - c. Glycerin
 - d. Zinc oxide

Classified

PHARMACIST WANTED for full and part-time positions available. Benefits include health insurance, paid vacation and NO evening hours in a computerized independent pharmacy located on the Eastern Shore. Call Fred Beatie at (301) 742-1188 or (301) 742-0914 to discuss this exciting opportunity.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Horn and Horn Smorgasboard on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (301) 358-7036.

FREE CLASSIFIEDS. MPhA members may place a classified ad at no cost in the journal. Send your typewritten ad to 650 West Lombard St., Baltimore, Maryland 21201.

FOR RENT St. Thomas, U.S. Virgin Islands Condominium (weekly rental). Two bedrooms, two baths, overlooks the Caribbean on the beach. Ideal for two couples or family. Please contact: Dr. Steven J. Berlin, (301) 247-4770, evenings: (301) 252-7508.

FOR RENT: St. John, USVI, Gallow's Point—Oceanfront 1 bedroom condo with pool and daily maid service. Low airfare available. 10% discount to pharmacists. Call Richard Matheny (301) 948-8547.

FDA HOTLINE FOR AIDS information is 800-432-AIDS.

COMPUTERIZATION \$1,500 will equip your prescription department for computerization—Digital Micro 11/23, printer, CRT (2), modem, etc. Call B. Lachman at (301) 833-2122.

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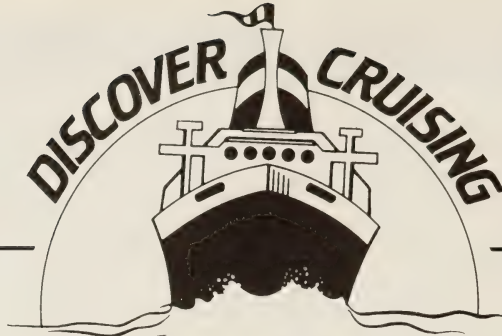
PHARMACISTS REHABILITATION COMMITTEE HOTLINE is (301) 727-0746.

LOOKING FOR AN OLD TIME PHARMACY? Late 1800's apothecary on O'Donnell Square in Baltimore, currently operating as a soda fountain and gift shop, with original wooden shelving, mirrors, marble, and fountain set-up is for sale by its current owners. The shop has been featured in a number of articles as well as on television. This is a rare opportunity to own a piece of pharmacy history. For more information, call Linda Smit at (301) 667-0653 or (301) 675-0059.

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VOL. 67

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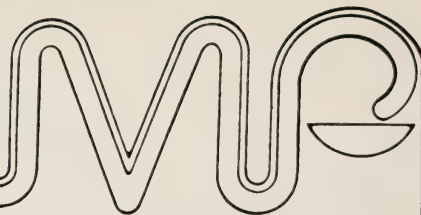
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The Maryland Pharmacist (ISSN 0025-4347) is published monthly by the Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201. Annual Subscription—United States and foreign, \$10 a year; single copies, \$1.50. Members of the Maryland Pharmacists Association receive The Maryland Pharmacist each month as part of their annual membership dues. Entered as second class matter at Baltimore, Maryland and additional mailing offices. Postmaster: send address changes to: The Maryland Pharmacist, 650 West Lombard Street, Baltimore, Maryland 21201.

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October is THE Month For Pharmacy

October is "Talk About Prescriptions" Month. This is a national event, sponsored by the National Council on Patient Information and Education, in an effort to educate consumers about medication. "Talk About Prescriptions" Month along with National Pharmacy Week, gives pharmacists an opportunity to be in the limelight with radio and television public service announcements and other publicity. Your patients will be targeted to increase their medication awareness by talking to their pharmacist.

Maryland is contributing to "Talk About Prescriptions" Month by celebrating Maryland Pharmacists Week, October 20 through 26, MPhA will be sponsoring several activities to promote pharmacy. This also gives us an opportunity to educate professional purchasers of pharmacy services. At the end of September, MPhA is sponsoring a seminar to educate benefit managers about appropriate guidelines for evaluating pharmacy insurance plans; that is, to examine the quality of the pharmacy services offered rather than the cost alone. For example, including drug utilization evaluation as part of the pharmacy service package can increase the cost-effectiveness of the benefit while also increasing the quality of care.

This month can give you the incentive to do something special for pharmacy within your own practice. Talk to your patients about their medications. Review your patient profiles for significant drug/drug or drug/disease interactions and inform the prescriber. Assist your patients with their over-the-counter medication selections.

To help promote "Talk About Prescriptions" Month and Maryland Pharmacists Week, this issue of *The Maryland Pharmacist* is filled with patient education materials, material source order forms, and ideas for you to use.

October is going to be a great month for pharmacy. Use it to build your practice, promote our profession and improve consumer medication awareness.

Ilene H. Zuckerman, Pharm.D.

President

Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Alzheimer's Disease, Part I: Pathogenesis, Symptoms and Outcome

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to explain the pathogenesis, symptoms and probable outcome of Alzheimer's disease.

Objectives

At the conclusion of this lesson, participants should be able to:

1. demonstrate an understanding of the probable causes of Alzheimer's disease and their relationships to other pathology;

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2. identify major signs and symptoms;
3. choose diagnostic criteria; and
4. select specific points of information to convey to interested consumers who inquire about this disease.

Background

The German neuropathologist and psychiatrist Dr. Alois Alzheimer first described the disease, that was to eventually honor his name, in 1907. Alzheimer described a patient, age 51, whose "...entire behavior bore the stamp of utter perplexity." The patient began to experience loss of memory and disorientation. After 4.5 years, she was bedridden and completely dependent upon others for care. It would take nearly 20 years before other scientists would accurately describe characteristic pathologic changes in the brain, and call the syndrome Alzheimer's disease.

Today, Alzheimer's disease is one of the more feared of all disorders that plague the elderly. Fear stems from the lack of accurate information about it, and fact that the disease course is often one of long-term decline toward death with the need for intensive personal care for the loved one who can no longer function on this own. Sadly, the disease completely immobilizes previously healthy and vibrant individuals so that they are totally dependent on others for their every need. In addition to sufferers *per se*, families of affected individuals who must helplessly watch them gradually regress to mental infancy and then death, must also be count-

ed among the victims. The Alzheimer's Association has published facts about the disease. These are listed in Table 1.

Incidence

As Table 1 illustrates, there is an estimated 4 million Americans over age 65 with Alzheimer's disease. Of these, approximately one million are affected with severe dementia (impairment or loss of intellectual capacity), with the rest suffering mild to moderate symptoms.

An additional 60,000 Americans in their 40s and 50s are also believed to be symptomatic. But while Alzheimer's disease may be diagnosed as early as the fourth decade of life, it is rare for these younger people to exhibit sufficient symptomatology to be officially diagnosed with the disease.

The incidence of severe dementia is reported to be about one percent of persons between 65 and 70 years, rising to nearly 15 percent in those over 85 years. In early 1990, as a result of an epidemiologic investigation of citizens in one community in Massachusetts, the overall prevalence rate for persons over age 65 was found to be much greater than suspected. In this self-contained community, the overall rate was about 10 percent, increasing from three percent for individuals aged 65 to 74 years, to approximately 18 per-

TABLE 1.

Facts and Figures About Alzheimer's Disease*

- Affects 4 million American adults
- Strikes women and men almost equally
- Usually occurs after age 65, although clinical symptoms may appear in individuals in their 40s
- Claims more than 100,000 lives each year
- Responsible for expenditure of more than \$80 billion each year

*Alzheimer's Association

cent for those aged 75 to 85, to 47 percent of persons aged 85 years and older. These new findings, if accurate, pose an even greater concern to the general public, given the widespread fear of Alzheimer's disease.

The most rapidly increasing segment of the American population, in terms of percentage, is the age group 85 years and older. It will undoubtedly increase even more, as greater numbers of Americans live beyond age 85. The public health impact of Alzheimer's disease is of concern to health care planners and providers. It is possible that over one-half million more Americans will suffer from Alzheimer's disease soon after the turn of the century.

Costs

The estimated economic burden associated with Alzheimer's disease is staggering. The Alzheimer's Association reports that the disease is responsible for expenditures of more than \$80 billion each year. This includes costs associated with diagnosis, treatment, nursing home care, informal care, and lost wages. Nearly \$5 billion of the total is assumed by the federal government, with another \$4 billion by the states. Patients and their families shoulder the balance.

The vast majority of Alzheimer's disease patients live at home. It is estimated that for every one patient, three family members are directly affected emotionally, socially, and financially.

Symptoms

Symptoms of Alzheimer's appear so gradually that the disease is not noticed until many years after onset. Oftentimes decades pass before peculiarities in behavior and decreasing intellect are finally recognized.

In its early stages, mental impairment may be the only identifiable symptom. With time, it increases in severity. The first cognitive process to vanish is recent memory, with memory of the distant past retained the longest. Soon, patients cannot recognize their spouse and family. They become completely disoriented as to time and place. Speech and language understanding become impaired and it is difficult to perform even simple chores. Decisions and planning are made only with extreme difficulty. While some victims

become exceedingly restless, others show intense lassitude to physical and mental tasks. Activities that were formerly enjoyable are no longer pursued.

Personality changes are prominent. A previously gentle person may become hostile and abusive, prone to frequent outbursts. The Alzheimer's patient may be depressed, or experience delusions. Other times they are delirious, with paranoia, fearfulness, and outbursts of rage and violence. Delusions and assaultiveness are common, especially at night. As controlled behavior deteriorates, drug therapy may be necessary to prevent self-injury or harm to others, and to facilitate ongoing care and treatment. Eventually the patient may become mute, incontinent and completely vegetative, incapable of caring for himself.

When the disease onsets in old age, the average course from appearance of symptoms to death is about five years, with a range of about one to ten. The duration is longer when symptoms appear earlier in life. Patients ultimately become so debilitated by their disorder that they are unable to combat other diseases. Their actual cause of death may be an opportunistic infection such as pneumonia.

Drug-induced Symptoms. Drug therapy for another condition may induce dementia in a previously healthy individual. A typical scenario describes a person with mild, but yet undiagnosed cognitive impairment. The person receives a drug to treat another condition, which in turn precipitates aggression or confusion.

In another scenario, a patient who is already combative and aggressive is given a new agent to treat it, and becomes worse when the new drug is initiated. A classic example is encountered with nursing home residents who are given antipsychotic or sedative-hypnotic therapy such as phenothiazine or other antipsychotic derivatives. These drugs have anticholinergic properties which exacerbate symptoms of dementia. The possibility of drug-induced dementia is the primary reason why initiating therapy with centrally-active drugs must be undertaken starting slowly, and with a low dose. Any dosage titration upward must be done slowly and continued to the point where maximum benefit is obtained with minimal drug.

Table 2 summarizes the various phases in the advancement of Alzheimer's disease. In the early phase 1, neither patient nor family are aware that anything is wrong. Toward the end of phase 1, the patient may discover that learning or comprehending new facts becomes difficult. There may be periods of depression or anxiety.

In phase 2, the individual can still function close to normal but may find it difficult to make decisions. The patient may also require supervision in routine activities such as cooking and handling finances.

By phase 3, the patient experiences extreme difficulty in performing mental tasks. These difficulties include disorientation to time and place, having trouble remembering who people are, and appearing restless, depressed or extremely agitated.

Finally, in phase 4, the patient is completely dependent upon others for all activity.

Pathology

Alzheimer's disease is a progressive pathology that involves deterioration of brain cells. The vast preponderance of histologic changes are quantitative, rather than qualitative.

Three primary pathophysiologic aspects of patients with Alzheimer's dis-

TABLE 2.

Phases in Alzheimer's Disease

Phase 1

- Lasts 1-2 years
- Victims exhibit forgetfulness. Are concerned about their condition.

Phase 2

- Lasts 3-8 years
- Victims confused and deny memory problems. They ramble conversations. Social functioning is impaired.

Phase 3

- Lasts 1-2 years
- Victims exhibit wandering, impaired activities of daily living. May have angry outbursts. May be incontinent.

Phase 4

- Patient is completely dependent on others for care.

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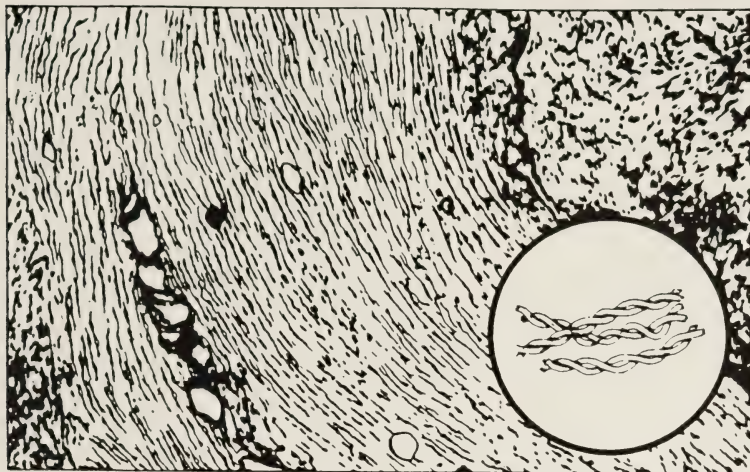


Figure 1. Schematic illustration of a neurofibrillary tangle from a person with Alzheimer's disease. Bundles of paired helical filaments in the neuronal cytoplasm are shown. The insert shows a high magnification of paired helical filaments in longitudinal section. Adapted from: Iqbal K, Wisniewski HM: Neurofibrillary tangles. In: Reisberg B (Ed): *Alzheimer's Disease: The Standard Reference*. New York, NY, The Free Press, 1983, pp 48-56.

ease include increased numbers of amyloid plaques (accumulation of glycoprotein) and neurofibrillary tangles, nerve fiber atrophy, and diminished acetylcholine transmitter activity. Each of these will be explained below.

The presence of neurofibrillary tangles (Figure 1) and neuritic (senile) plaques in the brain are characteristic of Alzheimer's disease. Neurofibrillary tangles are dense bundles of fibers within the nerve cells. They are seen most often in the cerebral cortex and hippocampus areas of the brain. These structures are comprised of paired helical (coiled) filaments that appear as tangled masses, loops or coils. It is believed they result from chemical alteration of a normal nerve fiber protein subunit. While neurofibrillary tangles also form with normal aging, their concentration is closely correlated with dementia in Alzheimer's patients.

The other major lesion, neuritic plaques, are found in the cerebral cortex. These are comprised of a central core of an amyloid beta protein, surrounded by numerous enlarged unmyelinated (bare) neurons. The amyloid beta proteins contain 39-45 amino acids. They are the primary constituents of neuritic plaques and cerebrovascular deposits in persons with Alzheimer's disease and Down's syn-

drome. Some authorities stress that this protein is damaging to brain cells. Its causative role in neuronal atrophy and pathogenesis of Alzheimer's disease is unknown at this time.

Neuritic plaques are also found in the brains of otherwise healthy elderly individuals. In persons with Alzheimer's disease, however, their degree of intellectual deterioration is directly correlated with the increased concentration of neuritic plaques within the cerebral cortex.

What is the acetylcholine link?

Exciting research over the past decade has identified deficiencies of 10 to 30 percent in concentration of the enzyme choline acetyltransferase in the brains of Alzheimer's disease patients. This is significantly below concentrations found in age-matched normal individuals. The enzyme is found in presynaptic cholinergic neurons and functions to catalyze acetylation of choline with acetyl coenzyme A, to produce acetylcholine. Acetylcholine is a neurotransmitter for conduction of nerve impulses from one nerve fiber to another in the central and peripheral nervous systems. Acetylcholine deficiency (cholinergic defect) may be at least partially responsible for impaired memory and other symptoms of Alzheimer's disease.

Other Associated Pathologies.

The primary deficiency of central neurotransmitter levels in Alzheimer's disease patients is acetylcholine (cholinergic). In addition, norepinephrine, gamma-aminobutyric acid (GABA), serotonin, dopamine, and glutamate are also reduced in some individuals. At this point, it is believed these other deficiencies result from previous cellular damage, and are not the actual cause of the disease.

High aluminum concentration in the brain has been implicated as a cause of Alzheimer's disease. Research from Canada in the mid-1970s demonstrated that these patients had excessive aluminum in certain areas of the brain. Investigators associated this high concentration with sites of pathologic abnormality in affected individuals. At the same time, Alzheimer's patients had lower than normal levels of aluminum in the cerebral spinal fluid.

This research remains controversial, since many more recent studies have failed to confirm the abnormally high levels of aluminum. At present, a high concentration of aluminum within the intracellular neurofibrillary tangles and extracellular neuritic plaques appear to be secondary to some other phenomenon, and not the cause of Alzheimer's disease.

Some investigators postulate that Alzheimer's disease is caused by a slow-acting transmissible virus. The discovery of submicroscopic proteinaceous infectious agents (prions) has stimulated much interest and research into how they may be an etiological cause of Alzheimer's disease.

Prions are smaller than viruses and devoid of DNA or RNA. Prions are known to cause several other degenerative brain diseases: scrapie in sheep and goats; chronic wasting disease in mule deer and elk; and kuru and Creutzfeld-Jacob disease in humans. Victims of kuru and Creutzfeld-Jacob disease have symptoms similar to Alzheimer's disease. At present, there is inconclusive evidence to support transmission of Alzheimer's disease from animals to humans, or from person to person.

There is convincing evidence that heredity is a factor in Alzheimer's disease. For example, the relationship between persons with Down's syndrome or Parkinson's disease, and Alzheimer's disease, is positive. Families with a high

incidence of Down's syndrome have a positive correlation with Alzheimer's disease. Furthermore, the number of individuals affected concurrently with Parkinsonism and Alzheimer's disease is greater than would be expected from the normal incidence of the two diseases alone. It may well be that a major etiologic distinction between Parkinson's and Alzheimer's disease is the area of the brain affected.

Current theory stresses that central nervous system degeneration associated with Alzheimer's disease is not caused by decreased blood supply into the brain. One form of pathology, known as **multi-infarct dementia**, is associated with cardiovascular disease. In this disorder, degeneration follows blockage of blood supply to the brain. The outcome is a type of stroke.

Since Alzheimer's disease does not appear to have a cardiovascular origin, vasodilator therapy is not considered to be effective. This concept will be discussed in more detail in Part II of this series. It is not unusual for patients to suffer from both Alzheimer's disease and atherosclerosis concurrently. These individuals are especially disadvantaged because brain damage can result from infarction. This would aggravate the existing cognitive deficit.

Diagnosis

Strong evidence suggests that Alzheimer's disease is not a single entity. Rather, it follows from a wide spectrum of pathologic events. Intensive research is underway to identify patient subgroups and specific drugs to maximize control of the disease.

Alzheimer's disease is diagnosed to greatest extent by excluding other causes. There is no specific diagnostic test or tool to differentiate it from other dementias. Extensive chemical, physical, neurological and psychiatric evaluations must be undertaken and the data evaluated to eliminate other conditions that mimic Alzheimer's disease. Some of these disorders include tumors, subdural hematoma, cerebral vascular disease, depression, Wilson's disease, endocrine disorders (e.g., myxedema), nutritional deficits, toxicity to drugs and alcohol abuse, and vitamin B₁₂ deficiency.

A physician who suspects that the diagnosis is dementia must determine whether it is reversible, or Alzheimer's

disease. Following the National Institutes of Health's consensus criteria for diagnosing Alzheimer's disease, it is possible to differentiate the disorder in up to 90 percent of cases. A definitive diagnosis can be confirmed by obtaining a brain biopsy, but this procedure is not performed routinely because of difficulties in technique. Consequently, diagnosis is based upon elimination of other disorders.

One important clue relates to the timing of onset of cognitive impairment. If it occurs with sudden onset, another problem, rather than Alzheimer's disease, is probably at fault. An important point is that Alzheimer's disease may actually be a heterogenous disorder with many subtypes. Among the subtypes that have been suggested are Alzheimer's disease grouped by age of onset, positive family history, presence of Down's syndrome, time course of progression, behavioral features, and the presence or absence of myoclonus or extrapyramidal syndromes.

Advising Patients

Oftentimes pharmacists' advice is conveyed to care givers, rather than to Alzheimer's disease sufferers. They should be advised to assure that the patient complies with the therapeutic regimen. The physician should be contacted for further advice as soon as any change is noted in the patient's mental or physical condition.

Stability in physical surroundings is important to disease sufferers. Care givers should attempt to monitor the placement of furniture and belongings, and to resist change that may further confuse the Alzheimer's patient.

Conclusion

This topic will be continued in Part II. In the concluding lesson, treatment will be emphasized. Specific information for patients and their care givers will also be presented.

When you don't know all the medicines your patients are taking, protecting their health is a crap shoot.



Many patients may be risking their health by combining prescriptions and/or OTCs that shouldn't be mixed. Uninformed medicine use is risky. Especially for older patients.

Counseling patients about all their medicines improves their odds of getting well and staying well.

Write to NCPIE for a free medicine counseling kit.



EVERYONE WINS WHEN YOU TALK

Please send me a **free** Medicine Counseling Kit.

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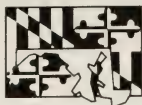
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Dickinson's Pharmacy

Jim Dickinson

Can patients be trusted? "Our pharmacy has always gone out of its way to accommodate customers, but we continue to lose them because of simple economics," wrote Nashville (TN) pharmacist Wade Wilson, in a July letter to *American Druggist*.

He was rebutting the testimony of the magazine's former editor, Leonard Gross, who urged pharmacists to become aggressive with patient-care services if they want to beat mail-order.

Wilson's point—shared by many independents—was that this idea is naive. "No matter how much service you give, if customers can get a three-month supply for \$5 instead of a one-month supply for \$70, they will do it."

Somewhere else, a few days earlier, I read a heart-wrenching letter from a retiree "customer" (ikkk! they're really patients!) apologizing to his pharmacist for going mail-order because he couldn't afford the \$2,000 a year he would have to pay otherwise for his maintenance medicines.

Surely you see what's happening here?

Patients, in their droves, are simply not fighting to keep their local pharmacies! I don't know what Wade Wilson has done to help them stay, but he probably figures it was all he could reasonably be expected to do—and maybe a lot more.

Simply put, I suspect that he and many others just don't trust the average Joe Customer to be loyal when a dollar gets in the way.

In *Pharmacy Practice* a month earlier, former *Drug Store News* pharmacy editor Harold Cohen,

R.Ph. (he once owned two independent pharmacies of his own) offered the advice that independents could team up with some of the smaller mail-order companies.

Cohen said such partnerships could let the far-sighted independent survive, since the onward growth of mail-order is inevitable; this way, they could at least get something out of the trend.

Now do you see what's happening here?

Pharmacy is divided—tragically, in my view—between those who seem to believe that if rape is inevitable, they might as well cooperate, and those who would follow Winston Churchill's thinking in World War II—"we shall never surrender!"

I suppose that's human nature. But rape victims seldom win, while Winston Churchill did. Pharmacists must decide which analogy fits. In times of great peril, all must weld together and fight like we know we can win.

That's what our country did in the Persian Gulf. Didn't it feel great to be an American? Doesn't it still feel wonderful—even though we maybe should not have pulled back as eagerly as we did?

Suppose we had done the other thing—let Saddam Hussein rape Kuwait, and Saudi Arabia too, and just try to cooperate with him?

In the case of pharmacy's war of survival against mail-order dispensing, pharmacists can weld together and win—if they have the will. And that might be the hardest part.

First, just say "No" to third-party plans that present, "take-it-or-leave-

it" contracts that aren't worthwhile. Most pharmacists don't do this, as happened recently in Virginia when the Blues offered two weeks to take or leave a contract with an AWP—minus 15% "walk-in mail-order" option that equated to Rx's worth only 20 cents apiece to the pharmacist.

As five-pharmacy owner Dan Herbert said: "I'd rather do that than give up those Rx's to mail-order—I want to keep those total profiles in my store." Herbert felt that the Blues were genuinely trying to meet competition by offering a mail-order option that could be fulfilled in the local pharmacy.

The Blues were in effect saying: "If Employer Inc. out there wants mail-order, we've got to give it to him even if we don't believe in it." With five pharmacies, comparatively minimal maintenance business and a substantial chemotherapy business, Herbert can probably afford to be charitable to the Blues.

Other pharmacies doing 40% to 50% of their business in Blues Rx's will close filling Rx's at 20 cents apiece—if significant percentages of their patients convert to the "walk-in mail-order" option or other plans that penalize local pharmacies.

Back to fighting (how does "Operation Pharmacy Storm" sound?). After just saying "No," pharmacists could get busy with their patients—explaining how important the unseen services are to them. Better yet, do this *before* you have to say "No"—it may avert the need!

Explain how drugs aren't just another grocery item . . . what profiles do . . . what would happen if the pharmacies all had to close through

lack of support . . . how creative financing (30-day accounts, self-billing to plans, etc.) can cover Rx costs and keep the pharmacy open . . . how the insurance industry's huge payrolls (12% of premiums) run up their (the patients') costs in higher deductibles and mail-order delays—have them write their congressman in support of H.R.9's repeal of the insurance industry's antitrust exemptions . . .

And pharmacists can support their state association's efforts to win the war of public opinion, and legislative opinion, so that patients don't have to face impossible choices.

The Florida Pharmacy Association's patient flyer campaign, *It's Wrong to Lose Your Rights*, packs a terrific punch for just \$15 per hundred—40,000 were snapped up in the first printing.

Don't give up—Never surrender. Patients can be trusted if you go about it the right way. You just have to arouse them.

This feature is presented on a grant from "Dickinson's Pharmacy—The Independent Voice," a professionally stimulating 8-page monthly newsletter available from Ferdic, Inc., P.O. Box 848, Morgantown, WV 26507-0848 at an annual subscription fee of \$45.



Everyone wins
when you talk...

**You & Your
Pharmacist—
Communicate
for Good Health**

When you have questions about your medicines,
who do you turn to?

The answer should be your pharmacist. If not, you may not realize what your pharmacist can do for you. Of course, he or she dispenses your prescription but this health care expert can also...

- detect possible harmful drug interactions with food or other medicines,
- advise you of the most effective nonprescription medicines to purchase,
- save you money by recommending the most cost effective medicines,
- save you money by ensuring proper use of medicines which cuts down on future health costs.

During National Pharmacy Week, October 20-26 and every other week of the year—**BE A WINNER AND TALK TO YOUR PHARMACIST!**

National Pharmacy Week *October 20-26, 1991*

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Annual Report of the Maryland Board of Pharmacy

Milton Moskowitz, Secretary

In compliance with the provisions as set forth in the Health Occupations Article Section 12-205 of the Annotated Code of Maryland, this report is submitted to the Honorable William Donald Schaefer, Governor of Maryland, the Secretary of Department of Health and Mental Hygiene, Nelson J. Sabatini and to the Maryland Pharmacists' Association. This is the eighty-eighth report to the Governor and Secretary and the seventy-sixth report to the Association. The report covers the activities of the Maryland Board of Pharmacy for the period May 1, 1990 to April 30, 1991. This report is also being submitted to the McKeldin Library of the University of Maryland, the Enoch Pratt Free Library, the Department of Legislative Reference, the Hall of Records and the State Library.

Meetings

During the year the Board held seventeen meetings, five of which were held at the School of Pharmacy of the University of Maryland, for the purpose of conducting examinations for licensure of pharmacists. In lieu of the regular Board meeting in November, a Regulatory Review was held.

Officers and Members

The Board consists of the following officers and commissioners: Steven S. Cohen, President, Milton Moskowitz, Secretary, William E. Adams, Leonard DeMino, Dorothy Levi, Theodore S. Litwin, Ralph Small, and George Voxakis. All of

the officers and commissioners are registered pharmacists in the State of Maryland with the exception of Mr. Litwin and Mr. Adams who are consumer (public) members of the Board.

Personnel

The staff consists of Roslyn Scheer, Executive Director, Brenda Askew, Secretary to the Executive Director and David Oliver, Secretary.

Examination

The Board conducted examinations for licensure of pharmacists during the year. They were held at the School of Pharmacy of the University of Maryland on June 26, 27, and 28, 1990 and September 25 and 26, 1990.

The applicants who were examined in June of 1990 were licensed in July, 1990 which is in F.Y. 1990. There were one hundred and fifty-two applicants for the Board in June 1990. One hundred and twenty-three passed both the theoretical and practical portions of the examination and were licensed. Twenty-nine failed the examination.

There were fifty applicants for the Board in September 1990 (F.Y. 1991). Thirty-three passed both the theoretical and practical portions of the examination and were licensed. Seventeen failed the examination.

Data relative to the June 1991 examination will be given in the next Annual Report.

The pharmacist licensure examination is given in two parts consisting of the following:

Part I—NABPLEX

Part II consists of:

Laboratory

Maryland Law

Federal Law

The NABPLEX and the Federal Law Exam are obtained from NABP. The Maryland Law Exam and the Laboratory Exam were compiled by members of the Board. The Laboratory Examination requires the compounding of four prescriptions per applicant. The following table shows the number of pharmacists who were licensed by examination during the past ten years.

Year	Number of Pharmacists
1980-1981	183
1981-1982	100
1982-1983	116
1983-1984	92
1984-1985	92
1985-1986	109
1986-1987	105
1987-1988	121
1988-1989	135
1989-1990	167
1990-1991	156

As in the past, many pharmacists applied for reciprocal licensure in Maryland in order to accept positions with their employers who have stores in Maryland.

In all cases, an applicant for reciprocal licensure must appear for a personal interview. The entire Board must act on whether or not to grant

licensure to such applicants, who must sign an agreement to comply with Maryland's laws pertaining to drugs and pharmacy.

The following table shows the number of pharmacists granted licensure by reciprocity and the number who were certified to be licensed by reciprocity in other states during the past ten years.

Fiscal Year	Reciprocity	Certification
1981-1982	85	51
1982-1983	103	60
1983-1984	119	58
1984-1985	148	54
1985-1986	191	70
1986-1987	206	75
1987-1988	197	57
1988-1989	228	86
1989-1990	187	103
1990-1991	212	98
TOTAL	1,676	712

The total table shows Maryland gained 964 pharmacists by reciprocity during the past ten years.

Pharmacy Permits

New permits to operate a pharmacy were issued to fifty-seven (57) firms as of April 30, 1991.

Of the fifty-seven locations that were issued permits, six were name changes. New permits were issued reflecting the changes.

Pharmacy Waiver Permits

In June, 1987, regulations were promulgated under COMAR, Title 10, Subtitle 34, Chapter 17, allowing waiver of full service requirements for recognized pharmaceutical spe-

cialties. As of April 30, 1991, the Board issued thirteen (13) new pharmacy waiver permits as follows: one (1) in Baltimore City; and one (1) in Allegany County, two (2) in Baltimore County, one (1) in Carroll County, two (2) in Howard County, and three (3) in Prince Georges County, one (1) in St. Mary's County, one (1) in Washington County, and one (1) in Wicomico County.

Manufacturers Permits

New permits to manufacture drugs, medicines, toilet articles, dentifrices, or cosmetics as of April 30, 1991 were issued to ten (10) firms.

Drug Distributors Permits

The Board issued thirty-one (31) new permits to distribute prescription drugs as of April 30, 1991.

Total Licenses and Permits

The total number of establishments licensed through the State of Maryland is 1,177 and the total number of pharmacists is 5,562 as of April 30, 1991.

Cooperative Activities

The Board maintained cooperative activities with the State Department of Health and Mental Hygiene, the University of Maryland-School of Pharmacy, the Maryland Pharmacists Association, the Maryland Society of Hospital Pharmacists, the Chain Drug Group, City, County and State Police and all Boards and Pharmacy Schools throughout the country. The Board has initiated

steps to work with Licensing & Certification to assist them in their inspection of pharmacy services in long-term care facilities.

Disciplinary Activities

The Board of Pharmacy receives complaints from the public concerning problems with the Board's licensees. Other complaints were received from the Division of Drug Control, Medical Assistance Compliance Administration, State of Maryland Courts and other state boards of pharmacy. The wide range of complaints varied in severity. Listed below are statistics concerning the types of complaints for the period of May 1990 through April 1991.

miscellaneous*	13
mislabeled prescriptions	2
incorrect drug dispensed	16
shortages of controlled drugs	3
communication	2
dispensing habits of pharmacist	15
fraud	2
professionally, physically or mentally incompetent	8
pricing	1
freedom of choice	2
Rx not dispensed	1
generic substitution	3
advertisement	2
theft of drugs	2
professionalism	6
duties of technician	3
TOTAL COMPLAINTS	81

*Complaints are on store hours, expired prescriptions, and security of drugs.

During the period of FY 1991, Twenty-five Orders were issued and distributed for public information involving pharmacists only. These include:

Pharmacist:

emergency suspensions	5
suspensions	3
suspensions with immediate stay and probation	8
revocation of license	4
full reinstatements	4
probation	1

Pharmacies:

emergency suspension	3
fined	1

During this period, the Board voted charges for violation of pharmacy law against thirty-one pharmacists and five pharmacies. Twenty-two pharmacist cases and four pharmacy cases have been concluded (included in the above statistics) and nine are still outstanding. Of these, two pharmacists' licenses are currently suspended on an emergency basis pending final resolution.

The Board has 16 additional outstanding cases from the previous year which have not been concluded.

Some pharmacists were convicted of violating more than one statute. Listed below are the types of violations according to the section of 12-313(b) of the Health Occupations Article and the number of pharmacists charged for each:

Aids an unauthorized individual to practice pharmacy or to represent that the individual is a	
(3) pharmacist	1
Provides professional services while using	
(4) any	4
Submits a false statement to collect a	
(5) fee	1
Willfully makes or files a	
(6) false report or record	2
Willfully impedes or obstructs the filing or recording of any	

(7) report	1
Without first having received a written or	
(14) oral prescription	7
Is professionally, physically or mentally	
(20) incompetent	2
Is convicted of or pleads guilty or nolo	
(21) contendere	3
Disciplined by a licensing or disciplinary authority	
(23) of any other state	2

Some pharmacies were charged with violating more than one statute. Listed below are the types of violations according to sections 12-409 and 12-501 of the Health Occupations Article and the number of pharmacies charged for each:

12-409	
prohibits a pharmacy from being conducted so as to endanger the public health or safety	3
(1) prohibits a pharmacy from violating any standards specified in 12-403 of this subtitle; or	2
(2) otherwise is not conducted in accordance with the law.	2
(3)	
12-501	

Whenever a pharmacy is in operation, it shall be constantly under the personal and immediate supervision of a licensed pharmacist.

Finances

All funds of the Board of Pharmacy are deposited to the credit of the Treasurer of the State of Maryland and disbursements covering the expenses of the Board are paid by voucher by the State Comptroller.

Financial Statement

The Board of Pharmacy had revenues of \$202,855 in 1989 and

\$234,580 in 1990. The Board of Pharmacy had expenditures of \$157,537 in 1989 and \$176,662 in 1990. The Board's budget is \$181,246 for 1991.

Regulations

The Board promulgated or amended the following regulations:

1. Parenteral/Sterile Enteral Compounding
2. Prescription Orders Transmitted By Facsimile Devices

Continuing Education

Throughout the year the Continuing Education Task Force has accepted requests for approval of Continuing Education (C.E.) programs, not automatically approved by the C.E. regulations. The first monitoring of C.E. documentation was completed without any pharmacists identified as noncompliant. Preparations are being made for the second monitoring to be done.

During this year the Board approved the first provider of continuing education that was not included in the regulations for the allowable two-year period.

Secretary-Treasurers Message

Every year for the past four years I have been given the privilege of writing an official message to the Governor and to the pharmacists of the State of Maryland. It's a challenge.

The workload of the Board is always full, be it legislation, disciplinary actions, licensing exams, meetings, hearings, testimonies, office procedures, permits, renewals, continuing education verifications, reciprocities, complaints, consent orders, committees or budget projections. The process goes on and there are always demands on the Board to promulgate regulations and monitor the practice of pharmacy. There is a continuous dialogue with associations, academia, State and Federal governments, as well as the public.

Many of you are aware of the State of Maryland's deficit. This has caused expenditures to be reduced and a freeze to be imposed on hiring.

The Board of Pharmacy has been directly affected. Previously four individuals worked in secretarial positions for the Board. Since November of 1989, two of those secretaries have left for better paying employment. Due to the hiring freeze, no one has been hired, or even interviewed, for the vacant positions. Now the Board's support staff consists of only two individuals: Brenda Askew and David Oliver. We greatly appreciate their commitment and dedication to the Board. Remaining staff, Board members, and volunteers are doing their very best to continue to provide services to licensees, applicants and the public. The current staffing level does not allow for work to be processed within the time frame you or we would like. We ask your understanding and patience during this difficult time. Yet we answer the demands asked of us and work with zeal and alacrity to accomplish each task.

We have the same members of the Board as last year, all of whom carried out their duties and various responsibilities with positive results.

Dorothy Levi: continues to serve as chair of the Continuing Education Task Force. She is the resource person for Continuing Education information and approvals. She has been instrumental in designing new pharmacy inspection forms which are now being considered by the Board.

Theodore Litwin: consumer member continues to be instrumental in developing quality assurance criteria for pharmacy services.

William Adams: consumer member has completed a consumer rights brochure that includes information consumers need to know about their prescriptions.

Leonard DeMino: continues to serve as a member on the Law Enforcement/Legislation Committee of the National Association of Boards of Pharmacy. He is a member of the Board's Licensing Committee and is working with the Division of Drug Control in developing a more flexible formulary so that pharmacists may substitute as soon as a generic is approved by FDA.

Ralph Small: continues to be our reciprocity expert and chief proctor for all licensing examinations.

George Voxakis: continues to serve on the Licensing Committee and reviews all inspection reports from the Division of Drug Control concerning community pharmacies. George's activity helps assure that appropriate pharmacy standards are met.

Stephen Cohen, President—has again been exemplary as chair of the Health Regulatory Boards Steering Committee. He continues to provide the focus for the Board of Pharmacy in all its deliberations. Steven has organized and implemented the institutional task force to draft Institutional Pharmacy regulations.

Roslyn Scheer continues in her 12th year as Executive Director of the Board. She lends a special dimension to the Board by her experience and knowledge of local and national pharmacy issues. She continues to serve on the Executive Committee of the National Association of the Boards of Pharmacy and brings a special prestige to the Board in this position.

The message I would like to give is that pharmacy is changing for the better. On April 30, 1991, the Governor signed a bill which I believe will have a significant positive effect on our future practice. House Bill 119, repeals a requirement that pharmacies have the most recent revision of the United States Pharmacopeial and National Formulary and instead requires that pharmacies keep a current reference library to meet the needs of the practice specialty of that pharmacy and the consumers it serves. The bill also requires the Board of Pharmacy to promulgate regulations for this purpose. This change recognizes that pharmacists need current information for their specialty. They will be better able to perform their clinical responsibilities and this will allow them to instantly share information with other health professionals and patients. Other legislation is listed and discussed in another segment of this report.

The Board formed a task force of

institutional pharmacy practitioners to draft Institutional Pharmacy regulations. These regulations will address the many broad and complex issues that face pharmacy practitioners in hospitals in the 1990's and beyond.

This year the Board has taken a vigilant approach in the application of corresponding responsibility by pharmacists in their dispensing of controlled substance prescriptions. We have written newsletter articles and have had many pharmacists appear before the Board to help them understand this law. Pharmacists must not accept a prescription as legitimate just because the physician wrote it. The pharmacist, in his professional judgment, must determine that the prescription is for a therapeutic purpose in the course of treatment. By law it is the responsibility of the pharmacist to also ascertain the validity of the prescription in clinical terms. The Board is particularly concerned about the pharmacists' understanding of corresponding responsibility because we believe it is an important component of pharmacy practice and for the safety of the public.

Once again, the Board of Pharmacy applauds the services of the Pharmacists Rehabilitation Committee for helping in the recovery of pharmacists who have a substance abuse problem. The Board has found the Rehabilitation Committee to be a very valuable resource in monitoring and evaluating pharmacists who are substance abusers.



Everyone wins
when you talk...

You & Your
Pharmacist—
Communicate
for Good Health

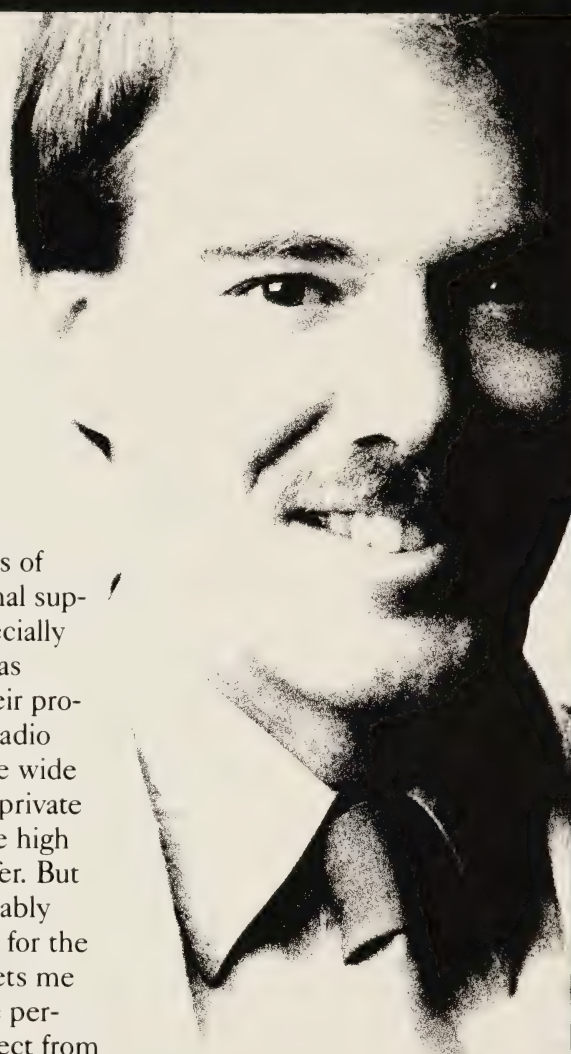
National Pharmacy Week
October 20-26, 1991

**"Over 3,000
pharmacies
belong to
Valu-Rite.
There must
be a reason.**

In fact, there are lots of reasons. Promotional support for example, especially now that McKesson has added cable TV to their program of circulars and radio spots. Then there's the wide selection of Valu-Rite private label products, and the high profit margins they offer. But most pharmacies probably sign on with Valu-Rite for the same reason I did: it lets me give my customers the personal service they expect from an independent, along with the low prices of a national chain. That's a combination that just can't be beat."



SCOTT RICKARDS
RICKSAVE DRUG
NAPLES, MAINE



McKesson

Fact Sheet

One of the major problems associated with the use of multiple medications is adverse drug reactions. Patients who use multiple physicians and pharmacists run the risk of receiving drugs that interact or that are duplicates of other drugs. This may result because the health care professional may not be fully informed about other prescriptions. In addition, the more prescriptions an individual is given, the greater the risk of medication errors and noncompliance.¹

This problem can be solved by using the pharmacist's expertise on prescription and nonprescription drugs, as well as for basic health information. However, this option can only be successful if there is face-to-face communication between the pharmacist and the patient.

SENIOR POPULATION

Adults aged 65 and older comprise approximately 12 percent of the population but receive 30 percent of all prescription medications.²

It is estimated that by the year of 2000 there will be 35 million older people, who will consume 50 percent of all prescription drugs.³

50 percent of the elder population do not take their medications as directed.⁴

PATIENT COMPLIANCE

- 7 percent of patients don't have prescriptions filled.
- 15 percent don't take the medication for the full designated time.
- 32 percent don't get refills, even though they need to do so.⁵

CONSUMERS AND NONPRESCRIPTION DRUGS

Only three percent of pharmacists feel that most consumers are qualified to choose OTC products without professional advice.⁶

19.6 percent of American adults are functionally illiterate (reading skill below fifth-grade level).

33 percent are reading at a level between the sixth and 10th grades. This raises serious questions regarding the consumer's ability to read and understand product labels.⁷

75 percent of patients are aware that their pharmacy keeps a complete list of their medications. However, only nine percent know to add nonprescription medications to their medication list.⁸

PHARMACISTS AS A SOLUTION

The magnitude of medication use by the elderly and the overall consumer use of nonprescription products suggest that unsafe or ineffective use of medicines can have a significant effect on individual health and health care costs.

Pharmacists can improve patient knowledge about medicines—prescription and nonprescription. If you don't know, ASK YOUR PHARMACIST because COMMUNICATION is the key to medication education.

Prepared by the
American Pharmaceutical Association.



Everyone wins
when you talk...
You & Your
Pharmacist—
Communicate
for Good Health

National Pharmacy Week
October 20-26, 1991

¹Healthy People 2000, Department of Health and Human Services, 1990.

²Ibid.

³Office of Technology Assessment. "Prescription Drugs and Elderly Americans: Ambulatory Use and Approaches to Medicare." October 1987.

⁴Priorities and Approaches for Improving Prescription Medicine Use by Older Americans, National Council on Patient Information and Education, October 1987.

⁵Schering Report IX, "The Forgetful Patient: The High Cost of Improper Patient Compliance," Schering Laboratories.

⁶OTC Labels: Can Consumers Read and Understand Them? American Pharmacy, Vol. NS30, November 1990.

⁷Ibid.

⁸Consumer Knowledge and Concerns About Medications, A National Consumer League Survey, February 1991.

PROMOTIONAL IDEAS FOR NATIONAL PHARMACY WEEK

The following events are suggestions to help create community awareness of the health services that the pharmacist can provide. The public can be informed and educated through the media and/or by personal contact.

1. **Select a spokesperson(s)** to visit classrooms and community groups. High school students would benefit from hearing about pharmacy as a possible profession. Furthermore, pharmacists can educate children on poison prevention and the importance of taking medicines correctly. Parents could also benefit from a course on how to educate their children about medicine use and what to do in case of a poisoning. The spokesperson could also highlight the pharmacist's expertise in helping the parent choose OTC products for their families. Elderly groups (nursing homes or civic groups) would also be a good target.
2. **Sponsor a "brown bag" medicine review.** This program invites patients to bring all their medications in a bag and discuss them with you. You can advise the patient on which medicines are out-of-date and alert the patient or physician of possible harmful interactions. A medicine review demonstrates to the community the pharmacist's knowledge, role as a health care advisor, and concern for community health. Contact the National Council on Patient Education and Information for guidelines (see insert that lists patient education and communication resources).
3. **Set up a booth in shopping malls or a special area in your pharmacy.** Distribute important health information like the brochure "Questions That All Patients Should Ask Their Pharmacist" and promotional items like buttons (see order form), pens, and pencils.
4. **Organize a health fair** to demonstrate how pharmacists interact with other health professionals to ensure the quality care of patients.
5. **Place an advertisement on a highway billboard** encouraging the community to talk to the pharmacist. If patients are aware that pharmacists can help, they'll probably ask. A local pharmaceutical company or health-related business may be willing to sponsor the project.
6. **Ask local merchants** to place the dates and theme of National Pharmacy Week on their marquees or electronic signs. Many banks have these signs and change them periodically.
7. **Select a media liaison** to contact the media with the news release (localize the provided sample and print on the enclosed news release paper) and radio PSAs. Provide the camera-ready logo and print PSA to the print media to make their efforts minimal. "How to Stock Your Medicine Cabinet," the "Pharmacy Fact Sheet," and the brochure of questions to ask your pharmacist will provide the media with facts and an angle for a story or mention.
8. **Write a letter to the editor** at your local newspaper encouraging consumers to inform their pharmacist of all their medicines (Rx and OTC) and to ask the pharmacist whenever there is any uncertainty about what they are taking. If your paper has an opinion/editorial page (Op-Ed), you can try to get the op-ed article by APhA President Marily Rhudy published.
9. **Radio station tie-ins** can provide a tremendous amount of exposure, including public service, paid advertising, on location broadcasts, and news coverage. Radio stations frequently cosponsor promotions with community groups. For example, if your pharmacy group can set-up a free cholesterol screening in a public place, it may be possible to get a station to promote use of the service during National Pharmacy Week. Station tie-ins can be generated by writing to the station manager, describing why the promotion is in the public interest and how the station can help. Furthermore, if your event offers a helpful community service, contact local television stations. Community service stories, especially with a good visual, have an excellent chance of being covered. You may also try for a listing in the TV station's community billboard.
10. **APhA Academy of Students of Pharmacy (ASP) Chapters** can be a great asset, that is, if there is a school of pharmacy nearby. APhA-ASP can also organize similar events for their campuses.

SAMPLE RADIO PUBLIC SERVICE ANNOUNCEMENTS

For broadcast: October 20-26, 1991

(60-seconds)

Do you ever have questions about the medicines you take? You should...and your pharmacist has the answers. It's National Pharmacy Week, and the nation's pharmacists urge you to speak up for your health. You need to know about possible side effects, about reactions with other medications, and about why your doctor's instructions are important. The person to ask is the one who was trained for just this purpose. Your pharmacist can also advise you of which nonprescription medicines to buy. Choose your pharmacist as carefully as you would choose your family doctor or dentist. He or she should be an important part of your family's health care team. Remember--when it comes to medications, what you don't know, can hurt you. So, during National Pharmacy Week and every other week of the year: *"Everyone wins when you talk...You & your pharmacist, communicate for good health."* This message is brought to you by the (local pharmacy organization) and the American Pharmaceutical Association.

(30-seconds)

Do you ever have questions about the medicines you take? You should...and your pharmacist has the answers. It's National Pharmacy Week and the nation's pharmacists urge you to speak up for your health. Pharmacists can tell you how to safely and effectively take what your doctor prescribes. Remember--when it comes to medications, what you don't know, can hurt you. So, during National Pharmacy Week and every other week of the year: *"Everyone wins when you talk...You & your pharmacist, communicate for good health."* This message is brought to you by the (local pharmacy organization) and the American Pharmaceutical Association.

(10-seconds)

It's National Pharmacy Week and pharmacists urge you to talk to them about your medicines. *"Communicate for good health."* This message is brought to you by the (local pharmacy organization) and the American Pharmaceutical Association.

#

Tips for having National Pharmacy Week Officially Recognized by Your State or Community

Getting a proclamation for National Pharmacy Week is pretty easy—if you know how to go about it. In many areas, a mayor or governor can issue a proclamation without action from the city council or state legislature. Following are some tips on how to get a proclamation issued with or without legislative action.

When a Public Official can Issue a Proclamation Without Legislative Approval...

1. Call your mayor or governor's office to determine how proclamations are issued. When you call, be prepared to find that the process may take a few months. Also, have your materials ready, such as the sample proclamation in this packet. Localize relevant facts about pharmacy and simply explain why National Pharmacy Week should be recognized by your city or state.
2. Try to elicit support from other leaders in your city or state. Your members can contact their mayors, city councils, and local and state officials about National Pharmacy Week. Letters to the governor from district pharmacy associations will reflect statewide interest and support.
3. When a proclamation is issued, express your thanks and appreciation. Include the governor and/or mayor in ceremonies planned for the week. Remember to inform the media about National Pharmacy Week and the official attention you have received. Finally, send a letter of appreciation to the official after the week's activities are over.

When Legislative Action is Required to Issue Proclamations...

1. If you need to work through the city council or state legislature, start now. Again, start by finding out what the process is for getting official recognition.
2. A resolution will need to be sponsored by a member of the appropriate governmental body. Find someone who is supportive of pharmacy or has voiced an interest in health care concerns. (This would also be a good time to educate a government official who has not worked with you.)
3. Again, have prepared materials for use in drafting a resolution or proclamation. Be ready to share your insight about pharmacy and the significance of National Pharmacy Week. For example, indicate how many pharmacists are in your city or state, the valuable contribution they make to the community, how much the resolution will mean to the (number) pharmacist voters and how this recognition might have a positive impact on overall community health.
4. Find out how you can help your sponsor ensure passage of the resolution. Like any bill you have to lobby, this will require a plan and some hard work. You may need to get other legislators to co-sponsor the resolution. You can start by writing your legislators about the resolution and soliciting their support. They may be in a good position to help your sponsor in moving the bill.
5. After the resolution is passed, show appreciation to your sponsor and to everyone who supported the resolution. Let your members know who these people are and how they helped. This information can be summarized in your newsletter. Invite your supporters to any activities you may be sponsoring and see that they are recognized at these events.

Everybody Needs a Leader.

Leader® Drug Stores offer the independent pharmacist a proven way to increase sales while maintaining local flexibility and community involvement. By taking advantage of the services

Leader has to offer, the independent pharmacist can better compete in the marketplace against national and regional chains.

Advertising.

Leader offers monthly high-quality, full color circulars with your store identification

— at a significantly reduced cost. Newspaper advertising kits, customized radio spots and a full line of in-store advertising materials and point of purchase displays *complete* the Leader advertising package.

Private Label Products.

With Leader, you can offer your customers top quality private label alternatives for 30% to 50% less than more expensive national brands. Not only do your customers benefit, but you earn higher margins on every Leader SKU. These products are made available exclusively to Leader member stores, and are backed by a money back consumer guarantee to ensure success at the store level.



A Powerful Image.

The look and prestige of a national chain are yours with the Leader store decor program. From bold, eye-catching exterior signs and awnings to customized interior fixtures, the Leader decor program offers only the finest in store identification customized to match your store's design and needs.



"It's Twins"®

The Leader "It's Twins" photofinishing program provides a vehicle to draw customers into your store. With the "It's Twins" program you can offer your customers quality double or giant prints at no extra cost. And to ensure the highest quality reproduction, Leader uses the Kodak Colorwatch™ System.

Buying Power.

With Leader, the independent pharmacist can purchase their products at prices usually reserved for chains. Besides buying power over the competition, Leader offers special and seasonal pricing, quick deliveries and flexible inventory management. Because all Leader member stores are independent, they can pick and choose which Leader programs are best suited to their individual needs. For more information on the advantages of the Leader Drug Store Program, call (614) 761-2001 today.



Everybody Needs a Leader.™

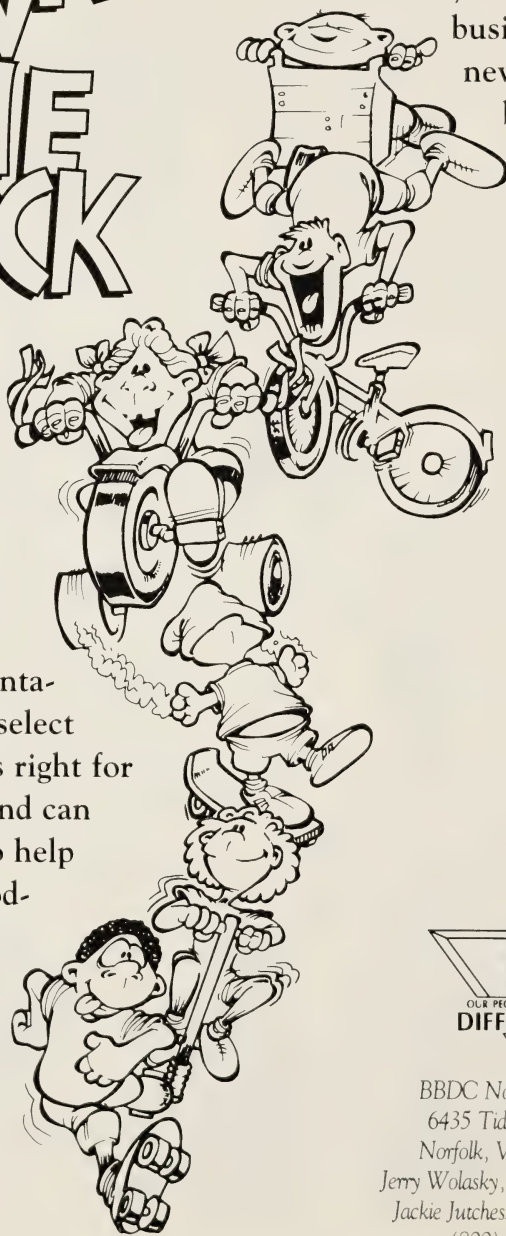
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We're Bergen Brunswig Drug Company. We've been serving pharmacies just like yours for over 100 years. Our professional sales representatives can help you select merchandise that is right for your trading area and can provide the tools to help you price those products competitively. Our merchandisers make sure that your products are effectively displayed for maximum sell through. Our drivers are

prompt and courteous. And, our customer service representatives are ready to answer your questions and inquiries. Bergen Brunswig Drug Company — we're your partners in business, not the new kids on the block.



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Jerry Wolasky, Division Manager
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Everyone wins
when you talk...

You & Your
Pharmacist—
Communicate
for Good Health

National Pharmacy Week

October 20–26, 1991

Communication Is The Key To
Medication Education.

**Talk to Your Pharmacist During
National Pharmacy Week,
and Every Other
Week Of The Year.**

Published by the
American Pharmaceutical Association



The National Professional Society of Pharmacists

*The mission of pharmacy is to serve society as the
profession responsible for the appropriate use of
medications, devices and services to achieve
optimal therapeutic outcomes.*

For another copy, send a self-addressed stamped,
business size envelope to:

National Pharmacy Week
APhA
2215 Constitution Avenue, N.W.
Washington, DC 20037

IF YOU DON'T KNOW...

ASK!

If You Care About Your Health—Learn About Your Medicines

- 7 percent of patients don't have prescriptions filled.
- 15 percent don't take the medication for the full designated time period.
- 32 percent don't get refills, even though they need to do so.

**Pharmacists can improve patient
knowledge about medicines—
Prescription and NonPrescription.**

If you don't know what to ask...

*Here are questions that all patients
should ask their pharmacist about their
medicine.*

Questions All Patients Should Ask Their Pharmacist About Their Medicine

1. What is the name of the drug product, and what is it supposed to do?

You should know the names of your medications, both prescription and nonprescription. Because you may see more than one physician, you should always inform your physicians of other medications you are taking. This will help ensure that the medication you take—both prescription and nonprescription—is appropriate for your condition.

2. When and how do I take it?

Correct use is a very important factor in ensuring that your medication gives you the help you expect. Examples of questions you might ask are: *Should I take this medication on an empty stomach or take it with food? Can I assume alcohol while taking this drug?*

3. How long should I take it?

Serious problems may result from not taking the medication long enough or by continuing medications too long.

4. Does this drug product contain anything that can cause an allergic reaction?

If you always patronize the same pharmacy, the pharmacist will keep your medical history and can help you avoid allergic reactions to the drug or inactive ingredients in your medications.

5. Should I avoid alcohol, any other drugs, foods, and/or activities?

Your prescription medication may interact with other drugs to cause a harmful effect. Certain **foods or alcohol may also interact with drug products**. Therefore, you should never begin **taking a new medication, prescription or nonprescription, without asking your pharmacist if it will interact with your other medications.**

6. What are the side effects of this drug product?

All medications can cause side effects, but they are not necessarily anything to be concerned about. Your pharmacist and physician can help you understand the side effects associated with your medication and help you deal with them. If you experience unexplained side effects, contact your physician or pharmacist.

7. What if I miss a dose?

We all try to follow the directions as closely as possible. However, we all occasionally make mistakes or forget to take our medications. The action to take after a missed dose depends on the drug. Therefore, ask your pharmacist his or her advice when you have the prescription dispensed. You should know the answer to this question before it happens.

8. Is it safe to become pregnant or to breastfeed while taking this medication?

Women should consider the possible effects of medications on an unborn child or a nursing baby. Most drugs cause no problems, but others can cause birth defects when the mother takes them early in pregnancy. Also, some drugs pass through a mother's system into breast milk. Therefore, expectant and nursing mothers should consult with their pharmacist or physician before using any prescription or nonprescription medications.

9. Is there a generic version of the drug product my physician has prescribed?

Your pharmacist can tell you if there is an approved generic version of your medication. Not all prescription drugs have generic counterparts.

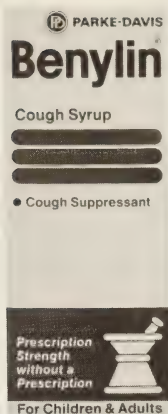
10. Are there any special storage requirements for my medicine?

Drug products may lose their effectiveness if stored incorrectly. The medicine cabinet in the bathroom is not a good place to keep medications because of the moisture and heat. Therefore, you should consult your pharmacist about the proper storage of all prescription and nonprescription drug products.

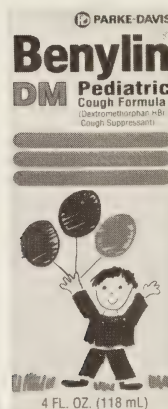
Pharmacists also provide additional services that can help you understand your condition and how to manage it and your medication. Ask your pharmacist questions—he or she has had five or more years of college to serve as your medication consultant.

Communication Is The Key To Medication Education. Talk to Your Pharmacist During National Pharmacy Week, October 20-26, 1991, and Every Other Week Of The Year.

Benylin.



Benylin, too.



Only Benylin® offers you two ways to turn off coughs*

Diphenhydramine

- **Benylin® Cough Syrup** relieves coughs due to the common cold or allergic coughs that occur in response to inhaled irritants

- **Benylin® Decongestant Cough Formula**, with the added ingredient pseudoephedrine, relieves coughs and nasal congestion due to colds and respiratory allergies

Dextromethorphan

- **Benylin® DM Pediatric Cough Formula**—new from Parke-Davis—relieves coughs due to colds and bronchial irritation up to 8 hours

- **Benylin® Expectorant Cough Formula**, with the added ingredient guaifenesin, relieves coughs complicated by upper chest congestion due to colds and bronchial irritation



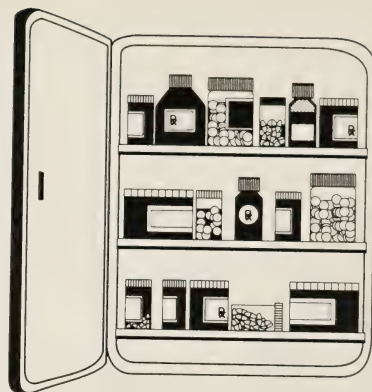
So stock up on and recommend Benylin—the only family of cough suppressants that offers you a choice of antitussives to individualize cough therapy. And because Benylin relieves symptoms so effectively, it helps your customers get the rest they need.

For free product information, simply complete and return the Benylin business reply card.

How To Stock Your Medicine Cabinet

Every household should have on hand some basic products to meet minor medical emergencies.

Pharmacists can advise patients on what products should be included.



✓ **Mercury thermometer (stubby or rectal)**

✓ **Assorted medical bandages**

✓ **Sterile gauze or nonstick pads (3" x 3")**

✓ **Surgical or first-aid tape**

✓ **Acetaminophen 325 mg (tablets or liquid)**

Analgesic of choice for children.

✓ **Ibuprofen**

Analgesic of choice for those over 12 years of age, if mild inflammation is cause of pain.

✓ **Brompheniramine 4 mg or chlorpheniramine 4mg**

These antihistamines relieve some cold symptoms, seasonal allergies, insect bites and various dermatitides. Ones that have the lowest incidence of drowsiness are Teldrin, Chlor-Trimeton, and Dimetane.

✓ **Antacid (e.g., Gelusil-M, Gelusil II, or Mylanta)**

In the case of acid indigestion, heartburn, or gastric upset, these antacids are preferred for taste and low sodium content.

✓ **Gastrolyte or Gatorade**

Short term therapy for replenishment of fluids in the case of diarrhea.

✓ **Poison kit (syrup of ipecac and activated charcoal)**
This is a must for any home with children.

✓ **Protective skin preparation (e.g. Keri or Curel Lotion)**
Either for weather-related or activity-related conditions that result in dry skin. Preferred products contain petrolatum and lanolin without fragrances and alcohols which may be skin irritants themselves.

✓ **Topical antiseptic and anesthetic (e.g., Bactine spray)**
For minor abrasions.

✓ **Cold-vapor or ultrasonic humidifier (optional)**
Many cold symptoms can be alleviated by proper use of moisture.

Reminder:

Humidity in a bathroom can decompose and change the effect of drugs. Medicine should be left in the original container and kept in a location that is cool, dry, out of children's reach, and dark to protect the medication from deterioration.

The specific products mentioned are recommendations and are not to be construed as endorsements by the American Pharmaceutical Association. Source: April 1989, *American Pharmacy*.



Everyone wins when you talk...

You & Your Pharmacist—Communicate for Good Health

National Pharmacy Week
October 20-26, 1991

*The Right
prescription for all
pharmacy owners...*

**THE MARYLAND PHARMACISTS ASSOCIATION'S
WORKERS COMPENSATION PACKAGE**

OFFERING AN IMMEDIATE **20% DISCOUNT** PLUS
ELIGIBILITY FOR UP TO A **25% DIVIDEND** AFTER
POLICY EXPIRES

Maintain the same coverage now provided by your
Workers' Compensation Insurance...BUT...
dramatically reduce your premium costs.

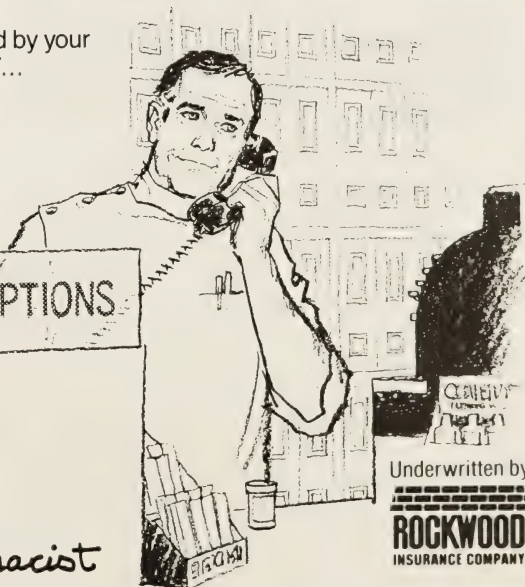
Now... Better Than Ever... Mayer,
Steinberg & Yospe is the best
prescription for insurance for the
Pharmacist.

**CALL US
TODAY...**

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Insurance for the Pharmacist

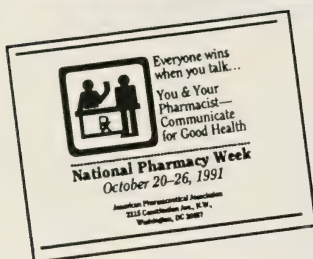


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ORDER FORM



Additional National Pharmacy Week Promotional Kits

Order additional kits for your committee members, local associations, and public relations liaisons. It's also a good idea to send individual kits to members of the media once you've completed the packet with information on your local activities.

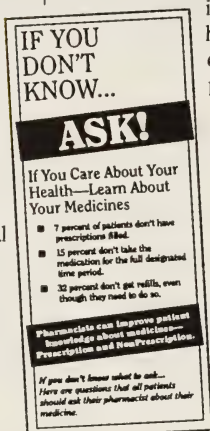
1-25 = \$4.00 each

26-100 = \$3.50 each

over 100 = \$3.00 each

Brochure: "Questions All Patients Should Ask Their Pharmacist About Their Medicine"

Provide an information service for your patients and other customers by including this brochure with an OTC or Rx purchase, or just offer them as take-aways. This brochure would be ideal to hand out at a health fair or a community health presentation.



100 or less = 25¢ each

over 100 = 20¢ each

Promotional Buttons

Capture the attention of your patients, customers, visitors and any other onlookers. Order enough for all your pharmacists, technicians, staff and/or members. These 2 1/4" safety pin-back buttons are designed with a red background and white lettering.

1 -100 = 75¢ each

100-200 = 70¢ each

over 200 = 60¢ each



Complete this form to order your National Pharmacy Week Promotional Items!

☐ APhA Member (ID# _____) ☐ NonMember

Quantity	Item	Unit Price	Subtotal
<input type="checkbox"/>	_____ Promotional Kits	_____	_____
<input type="checkbox"/>	_____ Brochure	_____	_____
<input type="checkbox"/>	_____ Buttons	_____	_____

Add \$2.50 for postage & handling or 10%, which ever is greater _____

(Allow 3-4 weeks for delivery.)

TOTAL

Name _____

Address _____

☐ My check payable to APhA is enclosed.

☐ Charge my:

☐ VISA ☐ MasterCard ☐ Amex

Card No. _____

Exp. _____

Signature _____

☐ Bill me (individuals only/maximum order, \$200/minimum order, \$25).

Signature _____

Street address required for UPS deliveries.

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Photos from the 109th Annual Convention appearing in this issue and in the August issue of *The Maryland Pharmacist* were provided by Larisa Kuntz. Ms. Kuntz is associate editor with APhA's weekly newsmagazine *Pharmacy Update*. MPhA's Annual Convention was featured in the July 8, 1991 issue of *Pharmacy Update*. Thanks Larisa!



President Ilene Zuckerman wields her gavel for the first time at the 109th Annual MPhA Convention this past June.



Trustees Ken Whittemore, Ellen Yankellow, and Lynette Bradley listen to the speeches at the final meeting of the House of Delegates.

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Continuing Education Quiz

The Maryland Pharmacist

SEPTEMBER 1991

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by January 31, 1992. A continuing education certificate for one contact credit will be mailed to you within 30 days. Please type or print clearly.

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Alzheimer's Disease, Part I

1. The pharmacologic activity of antipsychotic drugs that is most likely to exacerbate symptoms of dementia in nursing home patients is through their:
 - a. adrenergic action.
 - b. antiadrenergic action.
 - c. cholinergic action.
 - d. anticholinergic action.
2. Which of the following statements is true?
 - a. The vast majority of Alzheimer's disease patients are residents of nursing homes.
 - b. The greatest portion of the \$80 billion economic burden of Alzheimer's disease is paid by the federal government.
 - c. The most rapidly increasing segment of the American population is the group 85 years and older.
3. Which of the following is one of the three primary pathophysiologic aspects of patients with Alzheimer's disease?
 - a. Decreased number of amyloid plaques
 - b. Nerve fiber atrophy
 - c. Increased acetylcholine activity
4. Which of the following has shown the most convincing evidence of being a factor in Alzheimer's disease?
 - a. Aluminum
 - b. Decreased blood supply to the brain
 - c. Heredity
 - d. Transmission of a causative virus
5. In the usual progression of Alzheimer's disease, the first cognitive process to vanish is:
 - a. recent memory.
 - b. memory of the distant past.
6. Based on information in the article, the phase in the advancement of Alzheimer's disease that lasts 3 to 8 years, during which time the patient can still function close to normal but finds it difficult to make decisions, is referred to as:
 - a. phase 1.
 - b. phase 2.
 - c. phase 3.
 - d. phase 4.
7. The neuritic plaques found in the cerebral cortex of patients with Alzheimer's disease are comprised, to greatest extent, of which of the following?
 - a. Beta protein
 - b. Calcium deposits
 - c. Cholesterol
8. All of the following represent facts published by the Alzheimer's Association EXCEPT it:
 - a. affects 4 million American adults.
 - b. is much more likely to strike women than men.
 - c. usually occurs after age 65, but may appear in individuals in their 40s.
 - d. claims more than 100,000 lives each year.
9. The submicroscopic proteinaceous infective agent from viruses that is postulated to be involved in causing Alzheimer's disease is the:
 - a. deoxyribonucleic acid.
 - b. prion particle.
 - c. neurofibrillary tangle.
 - d. neuritic plaque.
10. A deficiency in which of the following enzymes in the brain of affected patients is most closely associated with Alzheimer's disease?
 - a. Aldehyde dehydrogenase
 - b. Carbonic anhydrase
 - c. Choline acetyltransferase
 - d. Pseudocholinesterase

Classified

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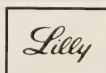
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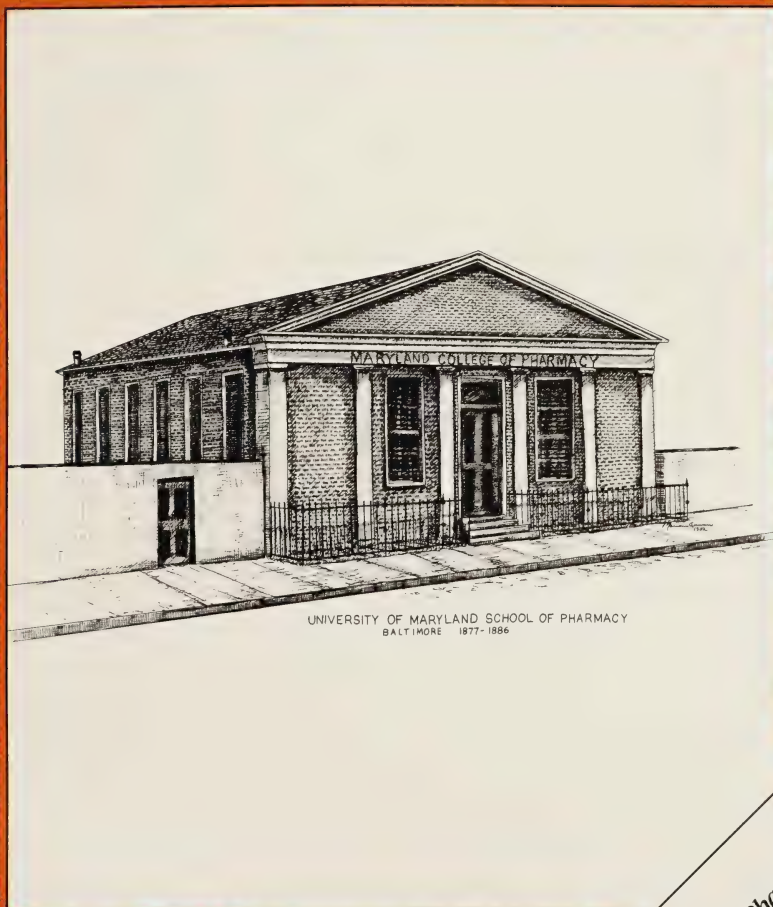
Commitment to Excellence

The Maryland Pharmacist

VOL. 67

October, 1991

No. 10



Welcome Back to Pharmacy School
Special Issue



OCTOBER 1991

VOL.67

NO. 10

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The Maryland Pharmacist (ISSN 0025-4347) is published monthly by the Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201. Annual Subscription—United States and foreign, \$10 a year; single copies, \$1.50. Members of the Maryland Pharmacists Association receive The Maryland Pharmacist each month as part of their annual membership dues. Entered as second class matter at Baltimore, Maryland and additional mailing offices. Postmaster: send address changes to: The Maryland Pharmacist, 650 West Lombard Street, Baltimore, Maryland 21201.

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Looking Inward For the Future

At the June Annual Convention, the MPhA House of Delegates adopted a resolution calling for the development of pharmacy practice standards. The concept of practice guidelines and standards in the medical care arena is not new. Standards have been utilized in quality assurance activities for years, including drug utilization review.

In the late 1970's, the American Pharmaceutical Association and the American Association of Colleges of Pharmacy developed and published "standards of practice" for the pharmacy profession. The American Society of Hospital Pharmacists has a history of practice guidelines development; recently published guidelines include those for pharmaceutical services for ambulatory patients.

There has been a recent surge in the interest of practice guidelines development; this resurgence is due in part to increasing fiscal restraints, growth of new technologies, and evidence of unnecessary treatment. In addition, current pharmacy regulations are inadequate in dealing with standards of practice. The OBRA 1990 legislation attempts to give guidelines for patient counseling; but, these apply only to Medicaid patients.

With the rapid growth of the concept of "pharmaceutical care," and the expansion of the pharmacist's role from a dispenser of medications to a role of accepting responsibility for the outcome of therapy, there is a need for practice guidelines. There guidelines should be comprehensive, specific, and inclusive of all relevant areas of pharmacy practice.

The development of these guidelines is not a task that should be taken lightly. So, under the leadership of Dr. William Heller, the Professional Affairs Committee will begin the task of practice guidelines development for pharmacy practice in Maryland. The Committee will review existing practice guidelines and standards, evaluate the current state of pharmacy practice, and take into account the growth of the profession and development of new technologies.

Practice guidelines development is a difficult, intensive project. However, if we don't initiate the task ourselves, others, (e.g., legislators, regulators) will do it for us. Through our professional associations, we can mold the practice guidelines to our needs, and to the best interests of the future of the pharmacy profession.

Ilene Zuckerman, Pharm.D.

President

Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Correspondence Course

Treatment of Fever Blisters with OTC Products: An Update

by J. Richard Wuest, R.Ph.,
Pharm.D.

Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

Goals

The goals of this lesson are to:

1. review recent findings on the etiology and treatment of fever blisters; and
2. review the pharmacology and therapeutics of OTC remedies for treating fever blisters.

Objectives

At the conclusion of this lesson, successful participants should be able to:

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1. differentiate between fever blisters and canker sores;
2. choose an appropriate OTC agent for treating fever blisters; and
3. know when to refer consumers to a medical specialist when self-treatment is not appropriate.

In January, 1990, the Food and Drug Administration (FDA) published proposed final rules to establish conditions under which OTC skin protectants and external analgesic drug products would be considered safe and effective for treating fever blisters. This culminated nearly a decade of intensive review of available information on these products following FDA's extensive system of: accepting reports from advisory panels; publishing comments to the reports from interested parties; publishing a Tentative Final Monograph (TFM); calling for additional comments on the TFM from industry, health care professionals, and consumers; and then, publishing the proposed rules.

If this category of drug product ingredients follows the norm to date, there will be another period for comments, followed by promulgation of the final rule which will define safe and effective ingredients for self-therapy of fever blisters, govern OTC labeling and manufacturers' claims, and regulate interstate commerce of external fever blister remedies. Oral agents which are claimed to be effective for treatment of fever blisters are still in review. The same is true for

external remedies indicated for treatment of canker sores.

Differentiating Skin Protectants from External Analgesics

In the current TFM notice, FDA defined drug products that provide a mechanical barrier to protect exposed skin surfaces from harmful or annoying stimuli as **skin protectants**. A discussion of specific ingredients considered safe and effective to self-treat fever blisters will follow later in this article. The overall group of skin protectants includes allantoin; aluminum hydroxide gel; calamine; cocoa butter; dimethicone; glycerin; kaolin; petrolatum; shark liver oil; white petrolatum; and zinc acetate, carbonate and oxide.

External analgesics are defined as ingredients that, when claimed to treat symptoms of fever blisters or cold sores, depress or stimulate cutaneous sensory receptors. External analgesics include local anesthetics such as benzocaine, butamben, dibucaine, dimethisoquin, dyclonine, lidocaine, pramoxine, and tetracaine, as well as certain alcohols and ketones such as benzyl alcohol, camphor, camphorated metacresol, juniper tar, menthol, phenol and resorcinol.

Oral agents (i.e., lactobacillus organisms and lysine) that are claimed to treat the symptoms of fever blisters were not addressed in the current TFM notice. They can continue to be promoted OTC until they are officially ruled on. If they are ultimately shown to be unsafe or ineffective, manufacturers will no longer be permitted to make therapeutic claims for them. If their efficacy is proven, however, manufacturers will then be permitted to promote them for this purpose.

Differentiating Fever Blisters from Canker Sores

Before discussing the treatment of fever blisters, it is appropriate to re-

Table 1

Differentiating Fever Blisters From Canker Sores

Symptoms	Fever Blister	Canker Sore
Pain	Intense	Intense
Fever	Yes	No
Halitosis	Yes	No
Salivation	Increased	No different
Malaise	Yes	No*
Other	Swollen neck glands	No effect on neck glands
Appearance	Yellow-white ulcer surrounded by red halo; gum margins swollen and red.	Gray to grayish skin lesions surrounded by erythematous halos. Usually 3 mm or more in diameter.
Contagious	Yes	No
Duration	10-14 days; healing without scarring.**	10-14 days; healing without scarring.**

*If condition is severe, malaise may be a symptom.
 **Large lesions may leave scars.

view canker sores and differentiate between the two. Since the terms fever blister and cold sore are synonymous, the designation fever blister will be used solely for the remainder of this article.

It is difficult to distinguish between fever blisters and canker sores (Table 1) because they are often confused for one another and referred to incorrectly. Nonetheless, each has distinguishing characteristics. Moreover, their causes and some treatments are totally different.

Canker sores (aphthous ulcers) are annoying, painful and recurrent ulcers that occur on the gums, lips, inner cheek, soft palate and tongue. From 20 to 50 percent of the population reportedly has experienced canker sores. They are not contagious, and invariably have an underlying cause that can be identified.

Fever blisters most commonly occur on the lips alone, or just inside the mouth. They, too, are irritating, painful and recurring. And they occur more commonly in cold weather.

Distinguishing between the two disorders with this terse information is difficult, but important to do so. As stated earlier, their treatment varies. Major factors believed to precipitate the disorders and means to control symptoms will be discussed as well as specific advice appropriate for patient counseling on fever blisters.

Ulcers on the lips and inside the mouth appear fairly commonly. Not all lip or mouth lesions are canker sores or fever blisters. Many diseases cause

them. For example, the lesions may signal an early symptom of several potentially fatal blood disorders, e.g., agranulocytosis. Several infective organisms also may incite them, such as the Coxsackie virus. Oral cancer normally appears initially as a mouth ulcer.

Oral cancer is of special concern because its causes are poorly understood. Symptoms include mouth ulcers that do not heal, persistent bleeding of tissues in or around the mouth, and swelling of the palate and other areas along with a feeling of numbness, pain and tingling.

In reality, there is no easy, consistently reliable method for distinguishing between fever blisters, canker sores and more serious oral disorders. If symptoms and lesion description match the information presented in this article, it may be a fever blister or a canker sore, but the symptoms can also be confusing. Bad breath, for example, is characteristic of fever blister formation, but it can also signal an oral bacterial or fungal infection. Whenever a mouth lesion fails to heal within two weeks or continues to bleed, professional consultation should be sought.

Canker sores vary in intensity from one person to another. The initial symptom usually consists of burning or tingling sensations in the area, leading to intense pain in the next 24 hours. At that time, an observable ulcer on the mucous membrane becomes evident.

Lesions are most common in the buccal and lip surfaces of the mouth. They range in size from 3 to 15 mm or

more in diameter, and may coalesce to form single, large ulcers which are much more painful and require a longer healing period than the smaller lesions.

Canker sores are characteristically shallow and ovoid in shape, and have a slightly raised yellowish border which is surrounded by a bright red zone. Generally, within the next week the lesion becomes crusted with a yellowish opaque substance that consists of dried tissue fluids, bacteria and white blood cells. Pain persists for several days, although a sensation of slight pressure or irritation often remains for several additional days. Recurring lesions typically become less severe with time.

It is not known what causes canker sores. Since *Streptococcus sanguis* has been isolated from many canker sores, some authorities contend that this organism contributes at least partially to the occurrence and problems encountered with canker sores.

A cell-mediated localized autoimmune reaction may be partially responsible for canker sore development. It has been demonstrated that lymphocytes taken from sufferers of recurrent canker sores have much greater cytotoxic action on mucosal epithelial cells in laboratory experiments, than lymphocytes removed from persons without canker sores.

What is a Fever Blister?

Fever blisters, like canker sores, appear most frequently on the lips and adjoining areas of the mouth. They are also irritating, painful and recurring.

It is estimated that at least one-half of all Americans aged 20 to 40 years have had a fever blister. Most victims were infected before age 5 years.

FDA defines them as vesicles that occur at the juncture of the mucous membrane and the skin of the lips or nose, and are caused by the Herpes simplex virus, type 1. Fever blisters are often referred to as **herpes labialis**. Another lesser used term is *Herpesvirus hominis*.

Unlike canker sores, fever blisters are highly contagious. They occur in a high proportion of individuals living under crowded conditions and heavily populated areas, and in persons of lower socioeconomic status. They are especially prevalent in areas of communal living, e.g., dormitories, prisons, nursing homes, etc. If a person residing in such



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surroundings develops a fever blister, they should take special care to avoid touching others while the active viral growth process is underway.

Fever blisters are characterized as yellow or white ulcers surrounded by a red halo. The margin of the gum in the immediate vicinity is swollen and red. As with canker sores, pain is intense. But unlike the former, fever blisters are accompanied by fever, increased salivation and mouth odor. Oftentimes the glands in the neck are swollen, due to the body's response to overcome infection. While they are also caused by contact with an infected person, generally this is due to transmission via saliva, fluids from a sneeze, or a seemingly harmless kiss.

There are a number of other members of the herpes family. The herpes simplex, type 1 virus is usually, but not exclusively, limited to non-genital areas such as the mouth, nose and eyes. Herpes simplex virus, type 2, usually, but not exclusively, incites lesions in the genital area. Resulting lesions are referred to as **herpes genitalis**.

Fever blisters are subdivided as to whether they are occurring for the first time, or are recurrent to previous fever blister lesions.

Primary and Secondary Herpes Infections

When fever blisters appear for the first time on the lips or nose, they are

referred to as primary lesions. If, by chance, the virus enters the circulation and causes generalized vesicular eruption on other areas of the skin, the infection is referred to as herpeticum eczema. The virus may also attack the eyes resulting in keratoconjunctivitis, a devastating infection which can lead to blindness if untreated. The virus can invade the central nervous system, leading to serious disease and permanent brain damage. This condition is referred to as meningoencephalitis.

Primary infections of the facial tissue are generally self-limiting and often mild enough that they do not cause irritating symptoms. Often an affected individual cannot recall when he experienced his first fever blister. When an infection occurs on tissue adjacent to the lips or nose or another area of the body, it is referred to as a **secondary infection**.

Once infection has occurred, the virus may remain dormant in the body for the remainder of the individual's life, often resulting in subsequent herpetic lesions. It is thought that, between bouts of fever blister flare-ups, the virus harbors within the sensory ganglia neurons of the trigeminal nerve that innervates the site of the primary infection. The body's defense mechanism normally keeps the infection dormant. But under certain stressful conditions, the immune response will be lowered or distracted, and recurrent lesions can occur. Table 2 lists factors known to activate recurrent herpes infection.

Humans can develop partial immunity to the herpes virus, type 1. Most children are born with the same level of passive immunity as that of their mother. By the end of the first few months of life, this immunity disappears. At that point, children are especially prone to development of fever blisters. Around age five active immunity begins to develop due to continued exposure to the virus. If the body's immune system is fully operational and responsive, it will provide the individual with immunity by adulthood. Persons experiencing a primary herpetic infection generally will suffer recurrences throughout life.

The localized area feels firm due to local edema. Shortly, solid elevations of the skin appear, then blisters form. The area may appear reddened, be-

Table 3

Safe and Effective Ingredients for OTC Fever Blister Remedies

External Analgesics

Local anesthetics
Benzocaine 5-20
Butamben picrate 1%
Dibucaine 0.25-1%
Dimethisoquin HCl 0.3-0.5%
Dyclonine HCl 0.5-1%
Lidocaine 0.5-4%
Lidocaine HCl 0.5-4%
Pramoxine HCl 0.5-1%
Tetracaine 1-2%
Tetracaine HCl 1-2%
Alcohols and ketones
Benzyl alcohol 10-33%
Camphor 0.1-3%
Camphor 3-10.8%
 with phenol 4.7%
Camphor 3-10.8%
 with metacresol 1-3.6%
Juniper tar 1-5%
Menthol 0.1-1%
Phenol 0.5-1.5%
Phenol 4.7% with camphor
Phenolate sodium 0.5-1.5%
Resorcinol 0.5-3%

Skin Protectants

Allantoin
Cocoa Butter
Dimethicone
Glycerin
Petrolatum
Shark liver oil
White petrolatum

cause of capillary dilation. Lesions may persist for several hours before the blisters break. At that time, they take on the characteristic yellowish crusted appearance. Recurring episodes are usually less irritating than the primary blister. For the most part, they are mild and little more than annoying.

Blisters should not be arbitrarily broken. The fluid contains the infective virus and can transmit infection to other areas or persons. When blisters rupture, the victim should take special care to minimize contamination of other parts of the body or other persons.

Lesions normally heal in 7 to 10 days without scarring or further problems. On occasion, secondary bacterial infection appears, especially if lesions are large. The presence of pus under the crust of a fever blister indicates possible bacterial involvement. Whenever healing doesn't occur within two weeks, the individual should

Table 2

Factors Known to Activate Recurrent Herpes Infections

Fever
Chilling
Sunburn
Windburn
Menstruation
Upset stomach
 or GI disturbance
Emotional stress
Excitement
Minor infections
Dental treatment
Allergy to certain foods
Any disease that
 increases metabolism
Fatigue

seek medical care. Persistent lesions may indicate the presence of more serious pathology.

Self-Treatment of Fever Blisters with Nonprescription Remedies

Although it has been vogue over the years to treat fever blisters with astringents and other agents that deprive the virus of moisture, evidence of effectiveness for this form of therapy has not been substantiated as of the publication of FDA's TFM. Currently, safe and effective therapy (i.e., Category I drug product ingredients) is limited to protectants and external analgesics (Table 3).

There are no specific remedies for curing or preventing fever blisters, so primary treatment is directed at relieving symptoms. This includes lessening pain and decreasing the duration of lesions, and providing a protective effect. FDA's conclusions follow.

Safe and Effective Skin Protectants.

Skin protectants that are safe and effective for self-treatment of fever blisters include: allantoin (absorbent); dimethicone (demulcent); cocoa butter, petrolatum, white petrolatum, and shark liver oil (emollients); and glycerin (absorbent, demulcent and emollient). These agents soften the crust on fever blisters and, therefore, relieve dryness. Their softening and moisturizing action keep fever blisters moist to prevent drying or fissuring. This, in turn, reduces the occurrence of secondary infections,

and offsets the delayed healing and discomfort caused by dry and cracked tissue in and around the fever blister. Manufacturers of OTC products will be permitted to claim that their products "soften crusts (scabs) associated with cold sores and fever blisters," and "relieve dryness and softens cold sores and fever blisters."

Safe and Effective External Analgesic Ingredients. Local anesthetics, and the alcohol/ketones listed in Table 3 are safe and effective for the temporary relief of pain and itching associated with fever blisters. The external analgesics cited in Table 3 can be combined with the skin protectants listed there also.

Other Ingredients. Drug ingredients that did not receive the safe and effective designation and cannot be labeled for treating fever blisters are antihistamines, hydrocortisone, and counterirritants. For antihistamines, the agency stated it had no basis to conclude that drug action on nullifying the effect of released histamine would relieve pain and itching of fever blister lesions. While antihistamines are claimed to be useful in alleviating some causes of itching and pain, there is no evidence of this specific use for fever blisters.

With respect to hydrocortisone, its current class labeling guidelines indicates that it is effective in relieving inflammation and itching of responsive dermatoses. Fever blisters are not responsive to steroids. Counterirritants were also judged to be inappro-

priate for use in treating fever blisters.

Two astringents that were identified as safe, but at present still unproven, were tannic acid and zinc sulfate. Further studies are required to prove efficacy before either astringent can be added to the list of allowable OTC fever blister remedies.

Patient Advice

It is difficult to distinguish fever blisters from canker sores. Consumers nonetheless often ask pharmacists for advice. The goal of therapy is to alleviate pain and help the body heal itself as much as possible. There are no remedies to cure fever blisters. Generally, treatment differs for fever blisters and canker sores. Pharmacists can use the information in Table 1 to help differentiate between the two conditions in order to decide which OTC product is best. OTC products listed in Table 4 are indicated for treating fever blisters.

Fever blister lesions should be kept moist to discourage cracking of the skin. Fissures increase discomfort, augment the chance for secondary infection, and prolong healing. Bland emollient creams serve this function. Products containing astringents should be avoided for treating fever blisters since they promote drying and cracking.

Fever blisters are self-limiting and usually clear within two weeks. Whenever they worsen with self-therapy, persist beyond two weeks, or continue to occur, medical advice should be obtained. Although they cannot be cured, fever blisters should not be ignored.

Table 4

Representative OTC Products Containing FDA-Approved Ingredients for Fever Blister Symptoms

Product	Ingredient(s)
Benzodent	Benzocaine
Blistex	Allantoin, camphor, phenol
Campho-Phenique	Camphor, phenol
Herpecin-L	Allantoin
Lip Medex	Camphor, cocoa butter, petrolatum, phenol
MG Cold Sore	Lidocaine, menthol
Numzident	Benzocaine
Orabase/Benzocaine	Benzocaine
Orajel Mouth-Aid	Benzocaine
Pfeiffer's Cold Sore	Camphor, menthol
Tanac	Allantoin, benzocaine

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A Glimpse At Pharmacy Practice Settings

Michele A. Zehm

Pharmacist. According to Webster, a pharmacist is a person trained in pharmacy; a druggist. Equipped with that definition, my mind conjures up an image of a middle-aged, kindly looking man in a white smock standing behind a prescription counter, carefully pouring an unidentifiable liquid into a graduated cylinder. I have no idea what he intends to do with that liquid—except pose for calendar photos—but it's apparent to me that this nice gentleman is the pharmacist who runs the corner drugstore. Modern pharmacy is a much more diverse profession than Webster ever imagined. Hence, we set out to investigate pharmacists who practice in non-traditional settings.

Retail Pharmacy

Thinking of the retail pharmacist as the guy in the white smock with the graduate in his hand is as passe as picturing the MD as a Marcus Welby look-alike wearing that strange-looking-shiny-metal-disc-fastened-to-a-headband apparatus around his head. (All of my life I've wondered what that headgear was for. A real doctor doesn't wear it, but it appears to be an integral part of the official "Doctor" costume at Halloween. The same goes for the

black bag, which I suspect is really a gym bag filled with tennis gear.) As we all know, retail pharmacy is outgrowing its "lick, stick" phase and becoming more clinical in its approach to pharmacy practice. It is not unusual for retail pharmacists, both independent and chain, to do nursing home consulting or to provide a variety of medical appliances and services for home use. Somewhat less common are retailers who have developed an interest in and knowledge of homeopathic pharmaceuticals. One such individual is Paul Hoffmann, RPh, of Port Washington, Wisconsin. Hoffmann offers several reasons for his decision to explore homeopathic remedies. He feels that homeopathic medicines appeal to his "naturalist" customers who are seeking non-chemical products. Hoffmann also considers these natural preparations to be another alternative for customers who have tried all of the traditional cures with no results. And finally, he believes that homeopathic products can be used safely by chronic disease sufferers, for whom most OTC products would be contraindicated.

Hospital Pharmacy

Hospital pharmacy, for years considered the only alternative to retail

practice, is not what it used to be. Hospital pharmacists are no longer condemned to the basement, next door to central supply, and down the hall from the morgue. These decentralized pharmacists work on the hospital floor, interacting with other health professionals.

Of course, somebody still has to see to the preparation of the drugs. According to a pharmacist at Abbott Northwestern Hospital, that "somebody" is being replaced by a "something." It seems that Abbott Northwestern, St. Paul Ramsey, and the Veterans Administration hospitals are employing robots in their pharmacies to relieve the pharmacists of the monotonous and laborious tasks of filling and checking the unit-dose carts.

The machine is called the ATC 212 (Baxter Inc.) and has 212 individual bins for the most frequently used drugs. It is hooked up to a computerized patient profile system so that every day, the robotic machine can custom package that patient's medications into a single unit-dose strip. Each unit in the strip is identified with the drug name, manufacturer, lot number, and expiration date.

While pharmacy technicians must still handle the injectable drugs and the less frequently used oral medica-

tions, the robots have proven themselves to be very economical in their role. It costs about \$.002 per unit to package drugs using the robotic system; traditional pre-packaged medications often cost from five to fifteen cents more per unit than those dispensed in bulk.

Pharmaceutical Industry

Pharmacy schools may be doing their students an injustice by neglecting to prepare them for jobs in the pharmaceutical industry, says Roy Hoff, RPh, President and CEO of Cima Labs., Inc. (a privately held pharmaceutical company in Brooklyn Park, MN). "It's like the world of industry does not exist (in their curriculum)—only retail and hospital pharmacy—and a lot of pharmacists work in the industry," observes Hoff. Cima employs another pharmacist as a research scientist exploring effervescent drug technology, the company's focus of activity.

The pharmaceutical industry utilizes pharmacist's skills in every aspect of their business from product formulation to sales and marketing. Minnesota is home to a number of pharmaceutical companies: 3M Riker; Upsher-Smith Laboratories, Inc.; Paddock Laboratories; Reid-Rowell; and MGI Pharma, Inc. to name a few. And of course, Gallipot Inc., second home of our past-president, Barbara Jones and her pharmacist-husband, Mike.

In addition to pharmaceutical companies, medical device companies such as Pharmacia Deltec employ pharmacists as liaisons with other health care professionals as well as the public. Pam Johnson, RPh, answers phone calls from across the country and explains how to dose insulin and morphine, and how to use Pharmacia Deltec's implantable devices for injectable drugs.

Nuclear Pharmacy

Nuclear pharmacists like Syncor's Dave Ziolkowski spend their time compounding and dispensing radio-pharmaceutical products for use in area hospitals and clinics. Most of the twenty or so products handled by Syncor's pharmacists are for IV

administration and serve a diagnostic rather than therapeutic role in patient treatment. Handling preparations of this type poses much less hazard to pharmacists than do those used for radiotherapy; still, Ziolkowski expresses his concern about the long-term effects of dealing with nuclear pharmaceuticals.

The Board of Pharmaceutical Specialties recognized nuclear pharmacy as the first pharmacy practice specialty in 1978. Pharmacists who wish to become certified in nuclear pharmacy must have completed 4,000 hours of nuclear pharmacy practice before taking the certification examination. Pharmacists who are hired by companies like Syncor, says Ziolkowski, must complete an extensive six-week training program at company headquarters prior to starting their employment. Much of the training deals with understanding the nature of radiation and the safe handling of radioactive materials. Few colleges of pharmacy offer specialized coursework or degree programs in nuclear pharmacy. The Nuclear Regulatory Commission (NRC) oversees the practice of nuclear pharmacy. To be recognized as a qualified nuclear pharmacist in the eyes of the NRC, one must complete 250 hours of classwork and 500 hours of on-the-job training.

Ziolkowski's pharmacy is open from 2:30 am to 5:00 pm, offers no opportunity to interact with the public, and requires employees who can pay careful attention to detail. In short, nuclear pharmacy is not for everyone. But Ziolkowski loves his work. One benefit, he adds, is not having to contend with third-party plans.

Consultant Pharmacist

Opportunities for consultant pharmacists are on the increase during this era of OBRA and other Health Department regulations. According to Rich Januszewski, RPh, co-founder of Health Care Consultants, his company began operating in November 1988 with a professional staff of one pharmacist and one nurse. Today he employs six pharmacists and three nurses and services 6,000 nursing home beds

within a 50-mile radius of the Twin Cities. Additional nursing home contracts are acquired at the rate of one every two to three months.

Januszewski feels strongly that nursing home consulting services—including resident drug review, quality assurance, and assessment meetings—should be provided separately from vendors who actually supply the drugs in order to eliminate any possible conflict of interest.

Unfortunately, pharmacy students do not usually have the opportunity to review the Health Department regulations in the same manner that they do the Board of Pharmacy rules. Because consultant pharmacists are involved primarily with Health Department regulations, Januszewski finds it necessary to give his employees additional training.

To be an effective consultant pharmacist, one should have clinical training but not necessarily a PharmD degree. Personality is probably the key ingredient, says Januszewski.

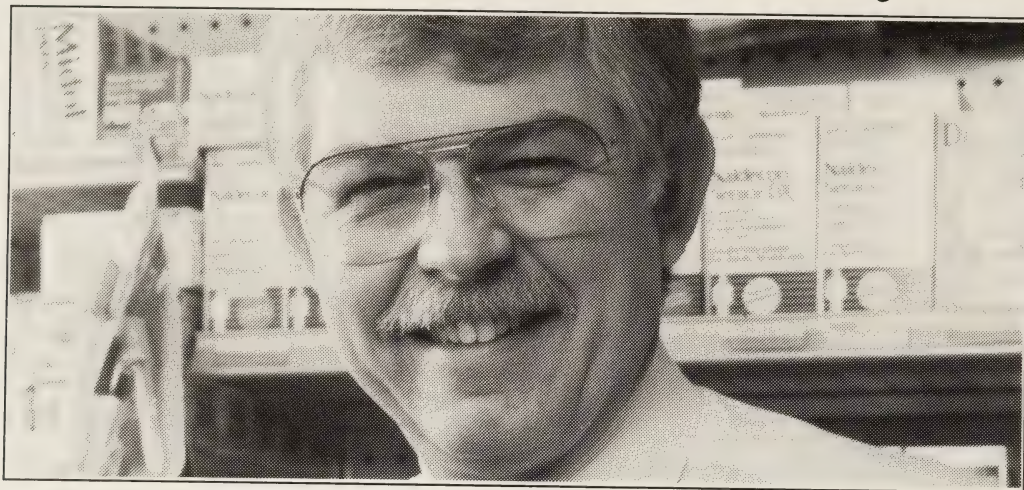
Government/Military

Prior to becoming an inspector for the FDA, Sharon Thoma, RPh, was employed as an Indian Health Service pharmacist on the Red Lake Indian Reservation. The Indian Health Service, like the FDA, the Center For Disease Control, the Coast Guard, the Bureau of Prisons, and the National Institutes of Health, is a division of the Public Health Service (PHS) which in turn is part of the Department of Health and Human Services. Surprisingly, the PHS is considered a branch of the military.

Joining the PHS is much like joining any branch of the military, says Thoma. PHS pharmacists are not required to attend boot camp, but do begin their service as an officer and are issued uniforms. Upon signing up, PHS pharmacists make a two or three year commitment which they are expected to fulfill. Contrary to common belief, pharmacists who serve in the PHS are not likely to be shipped off to a war zone, but are instead accommodated as much as possible as to their choice of location.

Most of the pharmacists who are

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affiliated with the PHS are employed by the Indian Health Service (IHS). Depending on the location, they may or may not live and work on a reservation, but they do serve only Native Americans. IHS pharmacists are an important part of the health care team, doing far more than dispensing drugs. They actively participate in patient treatment and take their turn at being on call. "It's a challenging experience I'll never forget," says Thoma.

Recent pharmacy graduates might be interested to learn that the federal government has initiated a pay back program that offers PHS pharmacists the opportunity to have government loans forgiven in exchange for time served. Interested? Sharon Thoma, by the way, is a recruiter.

Home Health Care

Specialized services such as home IV therapy demand the concentrated efforts of companies such as Caremark Inc., the nation's largest home IV provider. Caremark, whose state-of-the-art mixing facilities offer pharmacists clinical experience and exposure with physicians that enable them to rapidly advance into either a clinical or business role within the company. Another division of Caremark Inc., headed by Tom Blissenbach, RPh, area manager for the central region, takes care of schizophrenics in the notorious Clozaril Patient Management System (see September '90 *Maryland Pharmacist*).

Poison Control

Doug Borys is a member of an elite group of pharmacists. As Director of the Hennepin County Poison Control Center, he is one of only 15 poison specialists in the state of Minnesota. The nine pharmacists at Hennepin County Medical Center and the six at St. Paul Ramsey Medical Center provide poison information for the entire state.

Borys became interested in poison control in college, after hearing a lecture by Ed Krenzelok, an extremely talented and dynamic speaker who then occupied the position Borys now holds. As Borys later realized, getting a job as a poison specialist requires both patience

and luck.

A pharmacist who works as a poison specialist must be able to remain patient and calm in a crisis and be skilled in information triage. No matter how often he's handled a given situation, he must remember to treat each call as if it were unique, because to the caller, it is.

Nationally, nearly all pharmacist poison control specialists (not all are pharmacists; about half are nurses) have BS degrees, says Borys. On the job training at Hennepin County is intense, requiring about four to six weeks of instruction before a new employee is even allowed to answer a call in the presence of an experienced pharmacist. After two to four additional weeks of supervised work, the new employee will be allowed to answer calls alone. The poison control pharmacist should expect to work a full year before beginning to feel comfortable with the job.

"Just like any other pharmacy job, (poison control) is two hours of terror followed by two hours of catching up," says Borys. "But it is as good as pharmacy gets. We get to use clinical knowledge and act in a clinical role. We get the clinically oriented part, yet we still get a lot of interaction with the public, which is the fun part of working retail. We get the best of all worlds."

For pharmacists who can handle the job, work as a poison specialist is addicting. In Minnesota, there simply is no job turnover.

Board of Pharmacy

"In Minnesota we have a high standard of pharmacy practice. Our job is 80 percent education and 20 percent regulation," remarks Lloyd Pekas, RPh, inspector for the Minnesota Board of Pharmacy.

Pharmacists like Pekas who are employed by the pharmacy board feel that their job is to assist pharmacists with voluntary compliance, rather than to take a policing approach. After 14 years as an inspector, Pekas believes that he has developed a friendly relationship with pharmacists who have come to see him as a liaison between themselves and the board.

The Board of Pharmacy consists of the Executive Director, David Holmstrom; members of the board, all of whom are appointed by the governor; and three pharmacy inspectors. Although the board is a state agency, it is financed not through tax dollars but rather through independent appropriations and funding from pharmacy licensing.

To be a good inspector, a pharmacist must be sensitive, caring, knowledgeable, inquisitive and alert to problem situations. Pekas and his co-inspectors visit all pharmacy operations in Minnesota, as well as wholesalers, drug manufacturers, medical gas distributors, dispensing physicians and clinics, and nursing homes served by consulting pharmacists. In addition, they investigate complaints and answer a variety of questions from the public.

Pekas stresses that the primary purpose of the Board of Pharmacy is to protect the public. Without that obligation, there would be no reason for the board to exist. Helping pharmacists to comply with the law likewise helps Pekas to carry out his duty to the public.

Academia

Some pharmacists never get tired of pharmacy school, so they join the faculty. A few faculty members prefer to do research and teach because their position requires it of them. Others, like Linda Strand, RPh, PharmD, PhD, see themselves as a pharmacist first. "Academia only provides me the opportunity to teach other students to be pharmacists and to try to have a greater impact on changing pharmacy by doing research that focuses entirely on pharmacy practice," notes Strand.

In addition to teaching and doing research, Strand often works as a pharmacist in both the hospital and community settings for a very simple reason: she likes it. She sees no boundaries between pharmacy work, teaching, and doing research because they all share a common philosophy of pharmacy practice. Strand feels that getting out and practicing pharmacy the way it oc-

curs in real life gives her an advantage as a teacher; she can use real life problem situations to help her teach her courses.

"Pharmacy education is changing very rapidly. It has a long way to go in order to catch up with the realities of practice and with preparing students to do what society will pay them to do in the future," observes Strand. "If we teach what is practiced (today), we won't have practice sites for our students in two years because automation is coming."

In Strand's opinion, a PhD should not be reserved for the academic setting. She believes that pharmacists would have fewer problems if all PhDs, who are trained to systematically question and analyze, were more willing to use actual practice experiences to influence what and how they teach.

Managed Care

Group Health is one of the oldest Health Maintenance Organizations in the nation. It employs nearly 70 staff pharmacists, several pharmacy managers, and three pharmacy department administrators, all of whom are pharmacists. Kevin Navarro, PharmD, is the Assistant Administrator of Clinical Pharmacy Services.

Navarro's major responsibility is to furnish information to plan providers, pharmacists, and patients. She is also a member of Group Health's formulary committee and of the investigational review board whose job is to evaluate research. Finally, she is responsible for drug use evaluation and for establishing pharmaceutical guidelines for providers.

Managed care pharmacists like Navarro need excellent people skills in order to effectively deal with a wide spectrum of clientele. She finds it helpful to be able to listen carefully to a caller's problem (while sorting out the important information), provide reassurance, and resolve the situation as rapidly as possible. In that respect, Navarro is not unlike the poison control specialist when gathering information.

Navarro enjoys managed care be-

cause her work is challenging, fast-paced, and never repetitive or stagnant. The down side of her position is having to explain formulary decisions and defend the plan's pharmacy policies to individuals who are resistant to change. Navarro accounts for the high population of women in managed care positions like hers by explaining that it offers them a way to become involved in pharmacy administration that is often more appealing than retail or hospital management.

As medical technology progresses, Navarro believes that the role of the pharmacist in the HMO will become increasingly important. She expects pharmacists to become more involved in evaluating the overall impact of new treatment techniques on the total health care budget. For example, a costly new drug may be determined to be a justifiable addition to the plan's formulary if its use can prevent an extended hospitalization period for the patient.

Department of Human Services

Marie Nguyen, PharmD, is employed by the Department of Human Services as a Pharmacist Clinician. In that capacity, she is responsible for handling the drug formulary and for establishing pharmacy and DUR policy. The formulary committee refers its recommendations to Nguyen for acceptance or rejection.

Nguyen has both retail and hospital pharmacy experience, so even though she is, as she terms it, a "government bureaucrat," she tries to work cooperatively with the pharmacist. Nguyen frequently consults with other pharmacists for recommendations regarding drugs with which she is not familiar. To Nguyen's frustration, some of her projects have fallen by the wayside because of the recent implementation of the OBRA '90 regulations.

A pharmacist in a position like Nguyen's needs to be honest, firm, fair and even-handed, and willing to work very hard. Like many of us, Nguyen expected a job with the government would be pretty "cushy." She can now testify that her job is very demanding both in time and en-

ergy. Nguyen says that her PharmD degree prepared her well for the clinical aspect of her job, but she had little knowledge of state, federal, and health department regulations or the politics of government bureaucracy.

Correctional Institutions

Few pharmacists think of the prison system as a practice setting, but in speaking with Marie Nguyen, PharmD, I uncovered the fact that she was employed for a time at Oak Park Heights Maximum Correctional Facility.

According to Nguyen, the state prison system has a contract with the University of Minnesota to provide pharmacy service to the inmates. While employed there, she worked as a dispensing pharmacist in the in-house pharmacy and as a clinical pharmacist, making rounds with the physician and taking patient drug histories.

Nguyen was never concerned for her safety while at work because she felt appreciated by the inmates. "They know that you're there to help them, not to harm them. You would feel safer there than walking down Lake Street," observes Nguyen.

As you can see, pharmacists have the talent, ability, and opportunity to explore a remarkable variety of career paths. They may opt for a relatively traditional practice setting, focus on a specialized area of pharmacy, or become involved in a related field as a computer specialist or even a corporate executive. Some have used their pharmacy background as a starting point for future careers in business, medicine, and law.

Group Health's Navarro sums it up. "All around us there is so much we have to offer and now is the time that we can offer it. Finally, we can make an impact using all of the things we were taught in school. Pharmacists have been the wall flowers in the past, but now they're coming out and their dance cards are full."

Editor's note: Catherine A. Oslund contributed to this story.

AIM HIGH



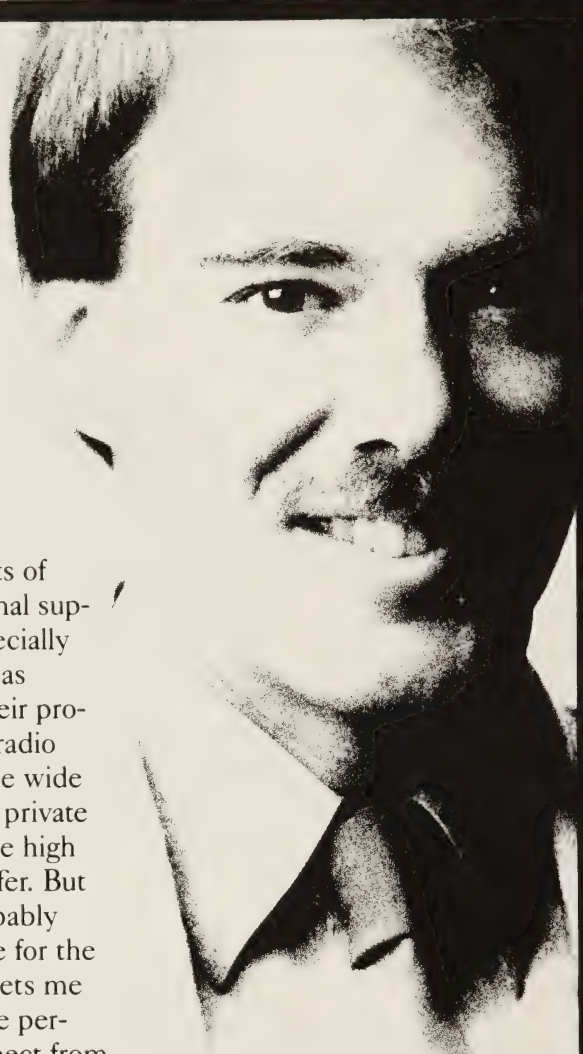
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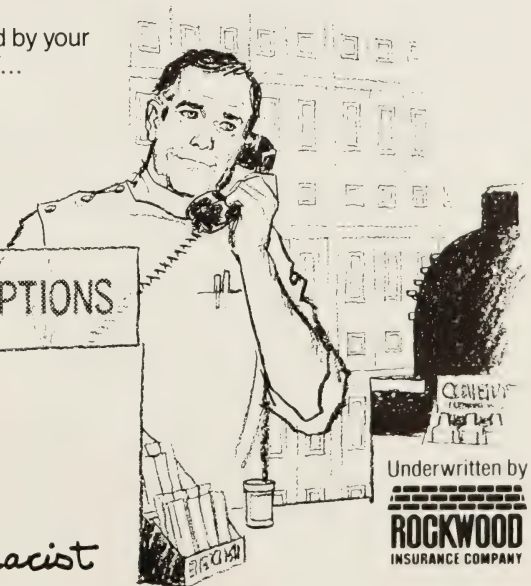
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Implantable Controlled Release Systems: Pharmaceutical Breakthrough Sparks Bioethical Debate

Suzanne J. Pierson, P.D.

A Tulare County California Superior Court Judge, Howard Broadman, this January ordered a woman convicted of beating her children to have the Norplant birth control device implanted in her arm for three years. This, after the Philadelphia Inquirer ran an editorial in December advocating that poor black women should use Norplant. The immediate negative response to these stories from bioethicists and the ACLU among others heralds only the beginning of what surely will be an important debate over the appropriate application of this new dosage form, in pharmaceutical terminology called an Implantable Controlled Release System.

An Implantable Controlled Release System (ICRS) such as that utilized in Norplant and for other drugs, provides for long term controlled release action from a single polymer matrix dosage form. ICRS differs from other controlled release systems such as nicotine skin patches, etc. in that it is implanted subcutaneously, on an outpatient basis. Norplant itself consists of six silicone capsules, each 3 cm in length containing levonorgestrel, a progestin which suppresses ovulation, affects uterine lining and achieves contraception. The medical advantages of this are numerous, including potentially fewer side effects, continuous and even drug levels, less frequent administration with corresponding complications and "improved" patient compliance. It is financially advantageous as well, being less expensive in terms of actual drug and medical personnel time.

It is its essential quality of being implanted surgically, its long duration of action, i.e. its "enforceable compliance" which has already attracted one judge to use it to enforce the societal wish of keeping an abusive mother from abusing any future offspring, in a fashion just short of sterilization. This form of forced contraception will most likely follow suit to failed attempts at forcing the use of existing contraceptive drugs and court-ordered sterilization, which was declared unconstitutional by the 1942 Supreme Court. It is not permanent sterilization, in that it may be removed by a doctor and fertility restored, and it is not (yet) unconstitutional

as a form of punishment or behavior control. But because it cannot be removed by the patient herself, it is as much a legal restraint on fertility as handcuffs on a thief. From the viewpoint of the experienced and often frustrated judge, such a guarantee on behavior control could seem highly attractive.

Is a drug approach to behavior change better than a potentially fallible attempt by social services? This may be the real question at hand. And, considering the endless variety of drugs which could be administered via this route, the number of adverse behaviors which attempts may be made to control seems as unlimited. Additionally, the track record of prison reform, drug rehabilitation programs, community mental health administration, etc., etc., for addressing *all* of the very large numbers of persons in need, will spur on the search for better, cheaper methods. Whether or not implantable controlled release systems are the answer or a gross misuse of these pharmacologic innovations will be the focus of growing debate as more drugs become available in this dosage form.

Already there are expressed fears by the black community that Norplant could be used as a form of genocide, or forced upon poor welfare women in general. In Florida, a judge imprisoned a cocaine-addicted woman because she abused drugs while pregnant. If this is allowable, would not coerced contraception for the habitual drug abusing woman? The Woman with AIDS?

Clearly, the desire of society is to enforce societal norms and prevent problems. Measures taken which essentially take over when the responsibility of the individual to that society ends, either because of fallible human nature or incapacity or perhaps criminal intent, may grow to include pharmacological ones. At that point new definitions of the rights of the individual to choose to act as they will, or "misbehave," even at the expense of society, will have to be reexamined.

Other drugs can also be incorporated into an ICRS, altering the target group. For example, the drug naltrexone (Trexan) which is a narcotic antagonist (meaning it

blocks the effects of narcotics and reverses the effects in the event of a drug overdose) is used to prevent drug-seeking behavior relapses in drug treatment. But because it has a very short duration of action repeat administration is necessary. The Dynatech Corporation has formulated several biodegradable polymer systems which deliver naltrexone for at least 50 days, and has tested them in primates. The implications of such a system in terms of legal consequence to the convicted drug user if it became available on the market would be dramatic. Coerced use of a narcotic antagonist could accomplish individual drug control directly instead of through means of punishment, which would perhaps better serve the drug pusher. The choice of punishment, incarceration or drug control may be offered in the future.

Another drug called disulfiram which is used to control use of alcohol, can presently be administered under court order or coercion in some jurisdictions and rehabilitation programs. Although questioned due to inefficient efficacy studies and risks of therapy, a new generation drug of its kind may be extrapolation eventually be used in an ICRS in response to alcohol abuse. An article in 1990 from the Swedish Journal *Tidskr Nor Laegeforen* reports clinical trials utilizing subcutaneous disulfiram implants. Although the study reported that the implants lacked significant pharmacological or clinical action, the motivation for the work, again, is clearly one of "enforced compliance" for alcohol rehabilitation.

Conceivably, the list of enforceable pharmacological behavior control modalities will grow in the future, creating an uncomfortable alliance between medicine and law, and assuring continued debates over the extent of their usage. Currently, long-acting injectable neuroleptic (antipsychotic) medications are available which may replace daily oral therapy. This may enhance compliance for the mentally ill patient, but put at greater risk his rights to decline treatment. Male sex offenders have been turned out of jail while using Depo-Provera, an injectable steroid, often termed "chemical castration." Many ethical and constitutional questions arose over this issue. The implantable systems will only complicate these questions because of their enforceable nature and long term effects.

New methods of drug delivery will revolutionize drug administration in the future, and most will lead to improved human health. There are exciting prospects for drug delivery system research in the battle against many diseases including cancer and AIDS. A recent study for example reported that implantable ceramic capsules may be used to deliver AZT in a controlled, safe and sustained manner in humans. There is no debate over the use of controlled release drug delivery systems to combat illness, but their intrinsic characteristics make them candidates for abuses which will have to be anticipated and dealt with by the pharmacy profession.

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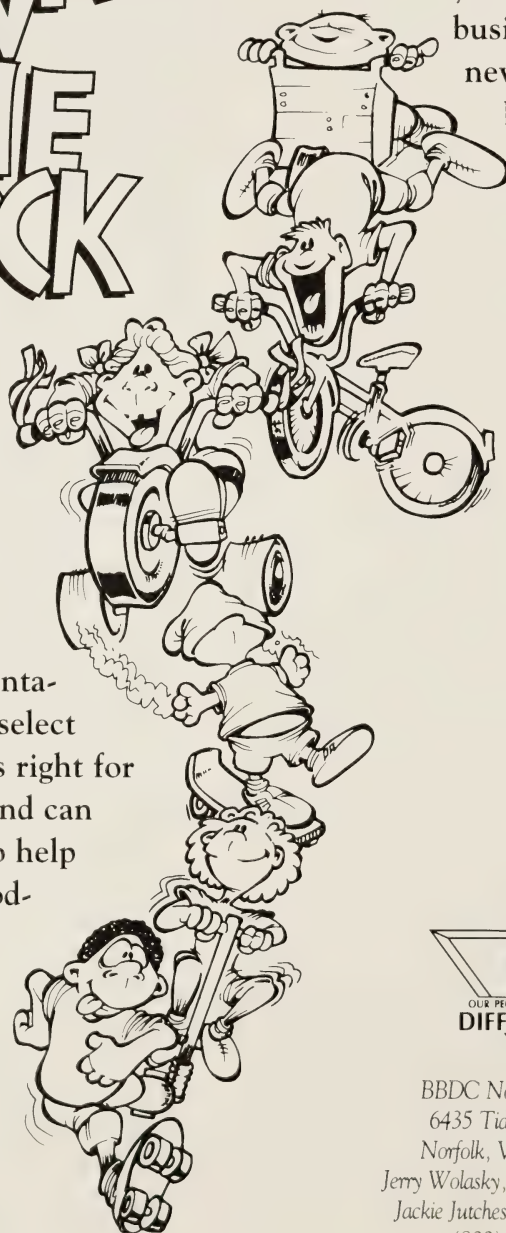
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Maryland's Entry Level Pharm.D. Program

David A. Knapp, Dean
School of Pharmacy
University of Maryland at Baltimore
Adapted from a Presentation to the
Maryland Pharmacists Association
House of Delegates, June 19, 1991

Thank you for this opportunity to come before you to talk about the School of Pharmacy's progress in planning a different kind of entry level Doctor of Pharmacy program for the profession in Maryland. I am here to strengthen our partnership for the future, and to build upon our solid first year of planning. I want to explain what we are doing at Maryland, why we are doing it, why we think we are on the right track, and why the School plans to move forward in partnership with MPhA and other state and national pharmacy organizations.

What Are We Doing at Maryland?

We are planning for a transition to an entry level Doctor of Pharmacy program. This is first among equally important of our School's strategic goals. Our planning has been going on for a year and will likely continue for another two years until we are satisfied with our new program and have the resources necessary to carry it out. Thus, the entry-level Pharm.D. program will not begin until at least the fall of 1993 and the first students will not graduate until at least 1997. Figure 1 illustrates our current planning timeline.

As you can see, we are planning to institute an initial course in curriculum-based continuing education in the fall of 1991 as well as instituting our GAPS grant on developing Pharm.D. experiences in the community. We hope to institute a pilot

program of a non-traditional Pharm.D. program in the fall of 1992 and our entry-level Pharm.D. program no earlier than the fall of 1993.

Some have asked us to put our entry-level Pharm.D. program on hold during the current economic downturn in Maryland. Since we are in the planning stage only right now, it is difficult to see what can be accomplished by putting anything on hold. Since we believe our goals are so important, it is essential that we continue our planning process in order to be able to implement the program as soon as we can.

I am pleased to report that despite the economic downturn, we have broken ground at UMAB for the Penn Street Building which will include two floors devoted to replacement and additional space for School

of Pharmacy programs, including Pharmacy Practice, Pharmacy Administration and Geriatric programs.

The planning phase for the entry-level Pharm.D. program involves four working committees, an external advisory committee, and an overall steering committee. The rosters of these committees are included in Figure 2. The committees have just reported on their first few months of work to the Advisory Committee which includes many MPhA members and is chaired by President-elect Nick Lykos. Our steering committee will be holding an all-day meeting in July to determine directions for the next few months.

The Curriculum Committee has completed its assessment of the current curriculum and has laid out the

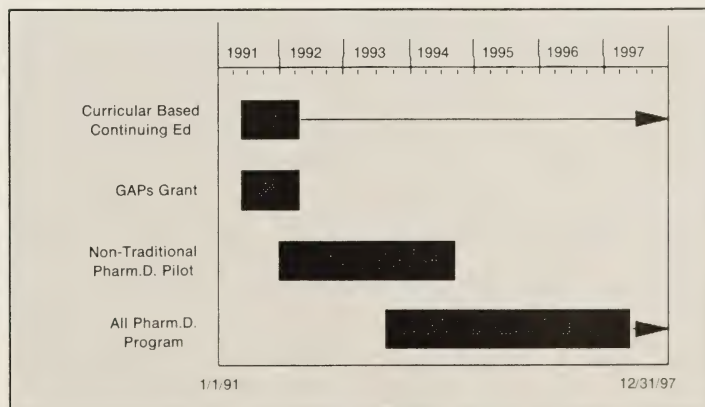


Figure 1. All Pharm.D. Transition Timeline

Steering Committee

Nicholas Lykos
David Knapp
Ralph Shangraw
Robert Kerr
Gary Oderda
Gary Hollenbeck

Transition Advisory Committee

Nicholas Lykos, Chairman
Patricia Ensor
Paul L. Jeffrey
Mark Levi
W. Irving Lottier, Jr.
Kathy Parker
Richard E. Rumrill
David Russo
Mel Rubin
Ralph A. Small, Jr.
William H. Stigelman, Jr.
David G. Miller
Susan Redmer
Stanton G. Ades

Student Affairs Committee

Robert Kerr, Chairman
Patrick Callery
Heinz Rosler
David Roffman
Joan Korek
Chul Kim
Robert Beardsley
Wes Glaudin
Kara Sink

Non-Traditional Pharm.D. Committee

Gary M. Oderda, Chairman
Larry Augsburg
David M. Arrington
Kathrin Kucharski
Dorothy Levi
Ralph Quarles
Kenneth P. Whittemore, Jr.
Beverly Yachmetz
Ilene Zuckerman
Mark A. Anderson

Practice Sites Development Committee

Ralph Shangraw, Chairman
William Heller
Paul L. Jeffrey
Robert Adams
Mona Gold
Leon Catlett
Joseph Ober
Fred Choy
E. Robert Feroli
Marvin Oed
Jerome Fine
Gail Rosen
Peter Lamy
Sidney Burgee
Matthew G. Shimoda
Belinda M. Tilley

Curriculum Committee

Gary Hollenbeck, Chairman
Gary Buterbaugh
Donald Fedder
Erkan Hassan
Robert Michoki
Marilyn Speedie
Lise Esser

Figure 2. Transition Committee Rosters

competencies to be required of graduates. It is planning a more flexible curriculum that will emphasize better preparation for ambulatory, institutional, and clinical opportunities. The curriculum will not simply be an additional year of clinical training added to the BS program, nor will it be the same as the current post-baccalaureate Pharm.D. program.

Areas of emphasis will be patient assessment, problem recognition and solving, prescriber intervention techniques, patient counseling, written and verbal communication, practice management, and marketing of professional services. These are areas of emphasis of concern to you as

demonstrated by the programming at this MPhA annual meeting.

The program will likely include about four more months of professional experience, including advanced rotations in community and institutional pharmacy, home health care and other areas.

A non-traditional Pharm.D. program is being planned by one of our working committees with emphasis on the earlier development of a pilot program for pharmacists working in community settings. A model curriculum geared to the needs of full-time practitioners is under development and an initial course should be available as an evening offering this fall.

We are also open to working with the profession on initiatives to establish measures of degree equivalency for current practitioners.

We have said from the outset that we would maintain class size at the size of our current BS class. Our current class of 100 represents a 25% increase over four years ago. We intend to maintain this class size as long as conditions warrant. Thus, the transition will not affect our entry level class size.

Finally, our Student Affairs Committee has studied phase-in plans for the new curriculum with an eye towards maximizing the number of graduates during the transition years. Thus, we do not anticipate a year with no graduates.

Why is Maryland Moving To An Entry Level Pharm.D. Program?

The reason, pure and simple, is that our faculty believes that doctoral level education is what is necessary to provide our students with the preparation that they need to lay the groundwork for 30-40 years of professional practice in pharmacy. As a faculty, it is our responsibility to look long term as well as short term. As the timeline illustrates, what we do to the curriculum today will not be reflected in graduates until almost the next century.

Pharmacy is the profession with the responsibility to help people make the best use of drugs. Drugs are already the most frequently used medical intervention and as the population ages and drugs become more complex, the need for pharmacists to aid in their use becomes even more critical. No other profession can do the job that pharmacists can. The growing evidence of the human toll of drug misadventuring demands that pharmacists step in and do the job. I urge you to read Henri Manasse's study entitled *Medication Use In An Imperfect World*¹ for a sum-

¹ Henri R. Manasse, Jr., *Medication Use In An Imperfect World*, Bethesda, ASHP Research and Education Foundation, 1989. (The monograph also was published as a two-part article in the May and June, 1989 issues of the *American Journal of Hospital Pharmacy*.)

mary of the data on drug use problems.

The number and complexity of drug products today place greater demands on our students. Biotechnology has stimulated an exponential growth surge in new products. These drugs are specific and require targeting to the needs of specific patients and are expensive, sometimes *very* expensive. Thus, the employment of doctoral level pharmacists to oversee their use is cost effective.

The pharmacist of the next century must rely on brain power for success. While supervision of the dispensing process must remain the responsibility of pharmacists, clearly the mechanics of dispensing does not. Technicians, robotics, unit-of-use packaging, and computer-controlled inventories will soon unlink pharmacy practitioners even further from the hands-on aspects of dispensing. Thus, the very survival of the profession of pharmacy depends upon adaptability and knowledge. We cannot send our young people into the next century without the ability and information to cope with change. We seek to educate professionals at Maryland, not to train assembly line workers.

Change can be scary for any of us. We resist it, we fight it, sometimes until it is too late. Pharmacy has fought similar battles over education before. In the early 60's, the curriculum went to 5 years but without a change in degree title. In Maryland, in the early 70's, the decision was made to incorporate 6 months of professional experience into the curriculum and eliminated the year-long internship requirement. On both of those occasions, the skeptics said:

What if you're wrong?

The benefits are unknown and unproven.

The changes are insupportable!

The changes will cost too much!

But look at the results! Look at the changes in pharmacy over the past decades: Increasing impact on health care; increasing influence on patient and physician decision-making; and increased stature in the eyes of the public.

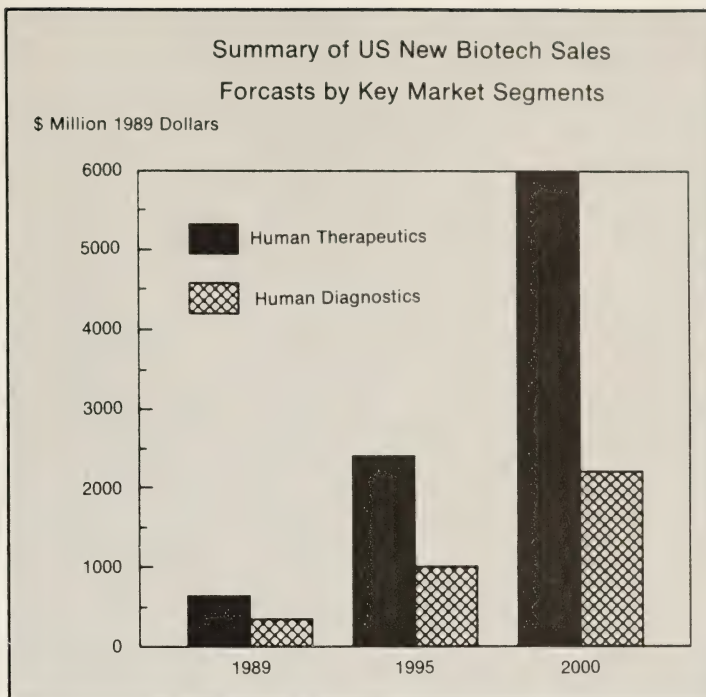


Figure 3. Biotechnology Sales Forecasts.

Change is uncomfortable, but change we must.

Why We Think We Are On The Right Track at Maryland

You have been told that a study by SRI² concludes that no more than 5 years of education is necessary to educate students for community practice and since most graduates go into community practice, there is no need for an entry level doctor of pharmacy program.

But the SRI conclusion is flawed! SRI did *not* do a thorough study of pharmaceutical education and, it is certainly *not* the only study that has examined pharmaceutical education. In fact, many of the statements made in the SRI report are similar to those found in the reports of other studies by other organizations. But other organizations have come to different conclusions. Let me quote from the SRI report:

A realistic future core role for community pharmacists is that of a 'drug use counselor.' The

major function would be to counsel patients about use of prescription drugs; this role would also include some monitoring of drug therapy in collaboration with physicians and patients to help optimize outcomes.³

That conclusion sounds like a call for doctoral level education to me! But the results of the SRI report have not caused NACDS, which is an organization of corporations that operate drug stores, to change its previously held position in opposition to entry level Pharm.D. programs.

Let's look at the position of some other groups, however.

The educational position of NARD, the organization representing independent pharmacists, is confusing. The group wants only one en-

² SRI International Final Report: An Assessment of Future Educational Needs for Community Pharmacists. SRI International, Menlo Park, California, 1990.

³ *Ibid*, p 11-1.

try level-degree, wants it offered in the same length of time (apparently five years), and wants it grandfathered to all current pharmacists. Since most current pharmacists already have the baccalaureate, it seems that the NARD supports an All Pharm.D. program if it can be accomplished in five years and if everyone is permitted to have the degree!

The American Pharmaceutical Association, *an organization of pharmacists*, has long endorsed the uni-

doctor of pharmacy degree. Its mission statement reads:

The fundamental purpose of the profession of pharmacy is to serve as a force in society for safe and appropriate use of drugs.

The Joint Commission of Pharmacy Practitioners, whose membership includes all of the national pharmacy practitioner organizations, has not taken a position on the degree issue but has adopted a mission

Note the support for entry-level doctoral education in pharmacy by those organizations in which pharmacists make the policy in democratic forums. Did the community pharmacists employed by NACDS member firms *make* the current policy espoused by NACDS? Did they even have a voice in the determination of that policy?

Let me say that I do agree wholeheartedly with one statement emanating from the NACDS 1991 meeting:

... decisions related to the curriculum and degree structure are properly left to the schools.

My friends, the University of Maryland at Baltimore School of Pharmacy is not alone in our assessment of the needs of the profession of pharmacy, its future direction and the desired shape of its future education.

Where Do We Go from Here?

The School of Pharmacy has put into place a planning process that involves all those who seek to participate. The working committees discussed earlier will be meeting throughout the next year. If you would like to serve on a committee and haven't been asked, please let me know. Representatives from the School are available to meet with any organization to discuss what we are doing, and your ideas and comments are always welcome.

The School of Pharmacy appreciates the support of the Maryland Pharmacists Association, as expressed by the simple, clear and ringing resolution passed at your 1990 meeting:

The Maryland Pharmacists Association supports the move to an All Pharm.D. program by the University of Maryland School of Pharmacy.

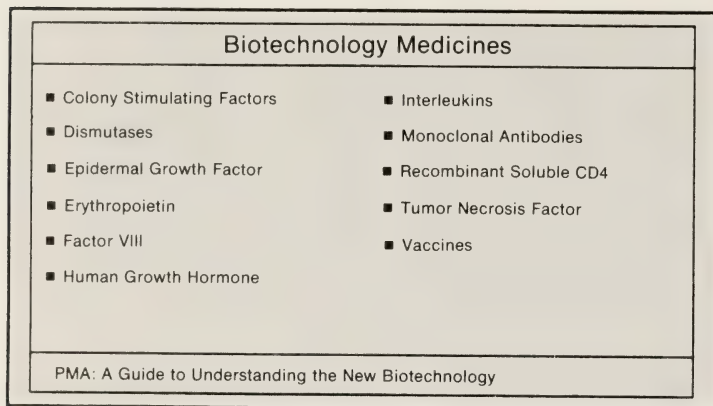


Figure 4. Biotechnology Classifications.

versal doctorate for pharmacists. Their Task Force on Pharmaceutical Education recommended such a position after conducting a thorough study of the issues in 1984.

The mission statement of the American Pharmaceutical Association reads:

The mission of pharmacy is to serve society as the profession responsible for the appropriate use of medications, devices and services to achieve optimal therapeutic outcomes.

ASHP, *an organization of pharmacists*, has endorsed the universal

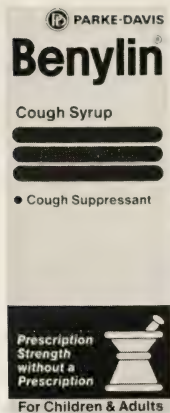
statement for pharmacy practice that reads:

The mission of pharmacy practice is to help people make the best use of medications.

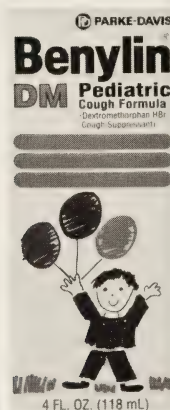
The APhA Academy of Students of Pharmacy, *an organization of pharmacy students*—the pharmacist of tomorrow—adopted a resolution at their March national meeting supporting

... a new doctor of pharmacy degree as the sole degree granted the students of pharmacy following the successful completion of their course of study.

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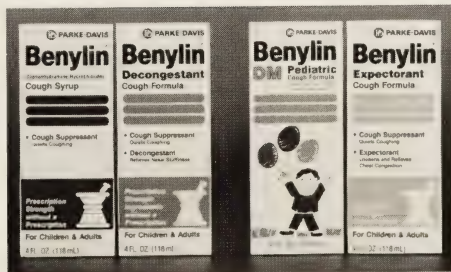
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Investing For Today

Consolidate Your IRAs for More Control Over Your Investments

Daniel K. Hays

Saving for retirement is the goal of nearly 75% of America's work force. When tax rules permitted all working Americans to place tax-deductible dollars into IRAs, many took advantage by establishing accounts in different financial institutions.

The Tax Reform Act of 1986, however, effectively "took the bloom off the rose" by negating tax-deductibility for many IRA contributors. At the same time, new regulations were put into effect that placed more accounting responsibility on investors and complicated long-range income and tax planning.

For instance, did you know that if

you place non-deductible contributions into IRAs, you must keep track of how much and when? This information is important because it will impact how much of your future withdrawals can be received tax free.

Were you aware that all IRAs must be added together when calculating the minimum mandatory annual IRA withdrawal, which is required to begin at age 70½?

Will you be affected by the "excess accumulation" rule where you pay an additional 15% tax on the funds withdrawn above certain amounts, which are indexed each year?

Changes such as these can often be confusing. Yet IRAs are still an attractive way to invest retirement money because earnings can grow tax-deferred. As a result, many IRA holders are looking for a simpler way to gain control of their investments.

Advantages of Consolidation into a Self-directed IRA

One of the easiest methods of achieving more control is to consolidate all your IRAs into one self-directed account that can benefit you in several ways. They include:

Lower trustee fees—One account means only one trustee fee. In some instances a trustee will not charge a set up cost and the annual maintenance fee can be as little as \$30.

Easier recordkeeping—Trustees usually provide information that explains your recordkeeping responsibilities and provides a convenient work sheet for tracking deductible and non-deductible contributions and account balances.

Improved service—Having just one trustee means only one phone call is necessary to obtain all the information you need. In addition, your financial adviser can field questions and provide personalized service to your IRA account.

Control over investments—A self-directed IRA lets you take charge of the investing of your retirement assets. For instance, you may prefer

professional asset management that is available through the purchase of mutual fund shares or you can arrange for personalized portfolio management.

Now that Congress is again addressing the question of incentives for personal retirement saving it may be a good time to reassess your IRA accounts and investments and make sure your retirement resources will be sufficient to fulfill your retirement goals.

IRA Legislation Update

In March, 77 senators co-sponsored a bill called the "Super-IRA-2," which offers incentives for people to save money. Because this bill could impact long-term income and tax planning for many of you, we have highlighted some of the key provisions of the proposed legislation. They include:

- Restoring the full tax deduction on contributions for all IRA accounts.
- Establishing a new type IRA account—the Super IRA—in which contributions would not be tax deductible but all distributions, including earnings, could be withdrawn tax-free five years after a contribution is made.
- Permitting penalty-free withdrawals for such purposes as first home purchases, funding higher education and catastrophic medical expenses.

Status of the Bill

At this time, the bill is still wending its way through the various senate and house committees as part of the legislative process. There appears to be broad bi-partisan support for the bill, which might increase changes for all or some of the provisions to be passed into law. We will keep you informed of further developments.

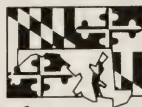
Daniel K. Hays is an investment consultant with Advest, Inc. in Lutherville, Maryland. If you have any questions, he can be reached at 800/272-7368.

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Continuing Education

Continuing Education Quiz

The Maryland Pharmacist

OCTOBER 1991

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by February 29, 1992. A continuing education certificate for one contact credit will be mailed to you within 30 days. Please type or print clearly.

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Is this program used to meet your mandatory CE? ☐ Yes ☐ No

Did this article achieve its stated objectives? ☐ Yes ☐ No

How long did it take you to complete the program? _____ minutes

Fever Blisters

1. All of the following are classed as safe and effective OTC analgesics for use on fever blisters EXCEPT:
 - a. mepivacaine.
 - b. lidocaine.
 - c. benzocaine.
 - d. juniper tar.
2. Which of the following symptoms differentiates fever blisters from canker sores to greatest extent?
 - a. Fever blisters cause swollen neck glands; canker sores do not.
 - b. Canker sores cause swollen neck glands; fever blisters do not.
 - c. Fever blisters cause intense pain; canker sores do not.
 - d. Canker sores cause intense pain; fever blisters do not.
3. All of the following terms refer to the herpes virus that causes fever blisters EXCEPT:
 - a. Hominis.
 - b. Simplex.
 - c. Labialis.
 - d. Zoster.
4. Of the following, which is classified as an absorbent, demulcent and emollient?
 - a. Allantoin
 - b. Dimethicone
 - c. Glycerin
 - d. Petrolatum
5. Patients suffering from fever blisters should be informed that fluid escaping from broken blisters:
 - a. is harmless and needs only be wiped off with a tissue.
 - b. contains the infecting virus and should not be allowed to touch any other skin surface.
6. The type of herpes virus that most often causes fever blisters is:
 - a. type 1.
 - b. type 2.
7. All of the following are classified as a safe and effective OTC skin protectant EXCEPT:
 - a. white petrolatum.
 - b. camphor spirits.
 - c. shark liver oil.
 - d. cocoa butter.
8. After a primary fever blister infection, the affected person will:
 - a. generally have recurrent fever blisters.
 - b. rarely have recurrent fever blisters.
9. Safe and effective OTC skin protectants reportedly accomplish all of the following EXCEPT:
 - a. soften fever blister crusts.
 - b. keep fever blisters moist.
 - c. prevent secondary infections.
 - d. prevent fever blister recurrences.
10. Keratoconjunctivitis refers to herpes virus infections that spread to the:
 - a. brain.
 - b. eye.
 - c. liver.
 - d. skin.

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Horn and Horn Smorgasboard on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (301) 358-7036.

FREE CLASSIFIEDS. MPhA members may place a classified ad at no cost in the journal. Send your type-written ad to 650 West Lombard St., Baltimore, Maryland 21201.

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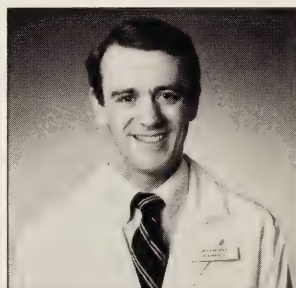
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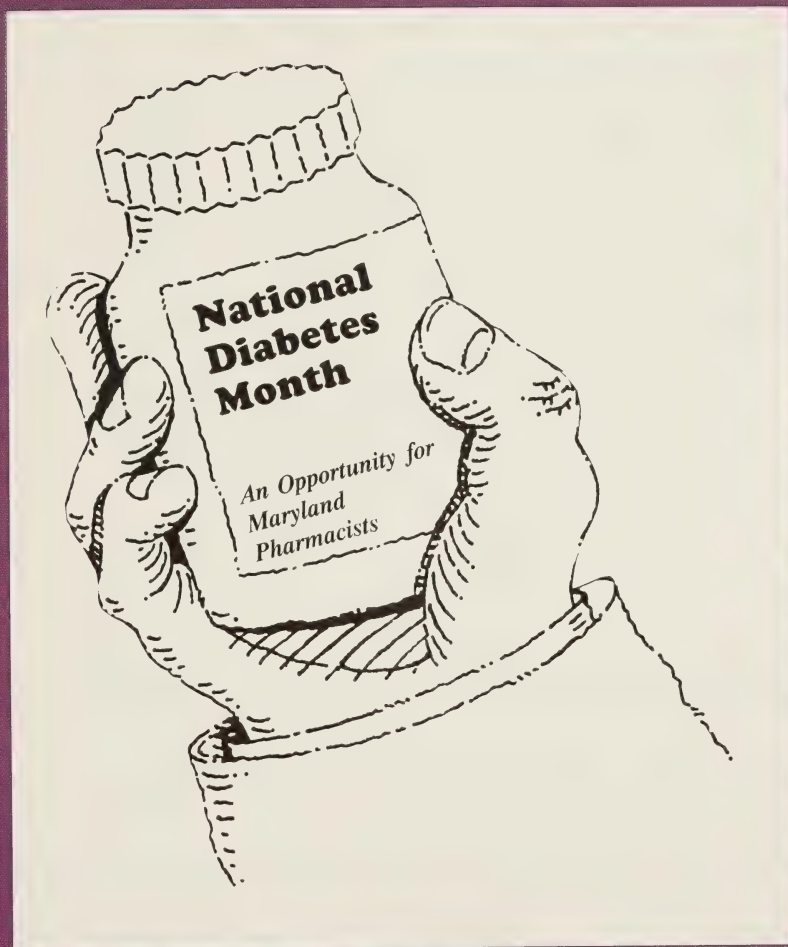
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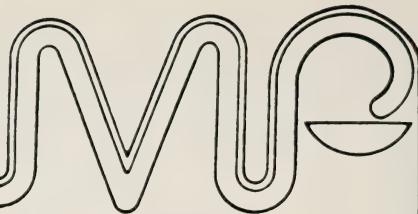
The Maryland Pharmacist

VOL. 67

November, 1991

No. 11





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The Maryland Pharmacist (ISSN 0025-4347) is published monthly by the Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201. Annual Subscription—United States and foreign, \$10 a year; single copies, \$1.50. Members of the Maryland Pharmacists Association receive The Maryland Pharmacist each month as part of their annual membership dues. Entered as second class matter at Baltimore, Maryland and additional mailing offices. Postmaster: send address changes to: The Maryland Pharmacist, 650 West Lombard Street, Baltimore, Maryland 21201.

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November is Diabetes Awareness Month

Diabetes mellitus (DM) is a chronic disease. We both know that. But examine the depth of that simple statement. From the moment of diagnosis forward, this person's life will never be the same. There are no vacations or holidays for diabetes. There's no "time off for good behavior." Every day is a new day, but the same challenges must be met.

From the moment of diagnosis, the individual has increased risk for cardiovascular disease, stroke, and blindness. The patient may ultimately have renal failure or an amputation. Chances are high a male with diabetes will become impotent.

From the moment of diagnosis the individual's fear and denial affect glycemic control. Cost of disease management (proper food, medication, supplies, etc.) affects glycemic control. Ignorance affects glycemic control. Frustration affects glycemic control. Interpersonal relationships and lack of support affect glycemic control.

Throughout their lifetime, the person with diabetes will see the pharmacist more than any other health care provider. How can the pharmacist serve these individuals? Consider the following:

1. Review new prescriptions for affects on blood glucose. Assess these affects for potential clinical significance.
2. Review OTC use. Watch for potential interactions and affects on blood glucose. Watch for use of harmful products such as wart and corn removers.
3. Keep adequate stock of important diabetic supplies such as meters, strips, lancets. Be aware of specialized devices which help the patient with diabetes. Such products include injection aids, pen injection devices, and insulated carrying cases for DM supplies.
4. Consider involvement in associations concentrating on diabetes such as the American Diabetes Association or the Juvenile Diabetes Foundation. Memberships include publications which have useful and practical information for practitioners and patients. Contact numbers are listed in this edition. In addition, these organizations often need pharmacists' involvement for professional and clinical issues.
5. Consider certification in diabetes education. The examination covers all aspects of care and management for individuals with diabetes. For further information contact the American Association of Diabetes Educators at 1-800-338-3633.

Above all, remember, diabetes is a whole life disease. It affects every organ and all aspects of one's life. When blood sugars are fluctuating and unstable, your patient is irritable. When sugars are high for long periods of time, your patient is extremely fatigued. Denial, frustration and depression are common with all chronic diseases, but particularly prevalent with diabetes. Develop empathy. Understand the disease, the disease process, and the impact on your patient and their families. These steps will open areas of pharmaceutical care which are very rewarding.

Beverly Yachmetz, Pharm.D., C.D.E.



Governor Proclaims Maryland Pharmacists Week

At a special ceremony in the Governor's Reception Room on September 23, 1991, Governor Schaefer proclaimed October 20 - 26, 1991 Maryland Pharmacists Week.

Present at the ceremonies were representatives from the Maryland Pharmacists Association, the Maryland Board of Pharmacy, and the Maryland Society of Hospital Pharmacists. *(left to right -- David Miller, MPhA Executive Director; William Adams, Commissioner, Maryland Board of Pharmacy; Roslyn Scheer, Board of Pharmacy Executive Director; Mark Levi, MPhA Board of Trustees Chairman; Governor Schaefer; Paul Weidle, MSHP; Paul Jeffrey, MSHP; and Michael Gum, MSHP.*

Photo courtesy of Richard Tomlinson, Governor's Press Office

Proper Handling and Disposal of Diabetes Supplies

Peter Yurkowski, PharmD
Candidate

Appropriate disposal of medical wastes, including used syringes and lancets, has become an important public concern. This is an obvious area of interest for the insulin-using patient. Because of the potential magnitude of the problem, the pharmacist and other health care providers should include information about appropriate disposal of contaminated supplies in educational sessions and when selling syringes and lancets.

Recent reports of syringes and other medical wastes washing up on shores have led to awareness of appropriate disposal measures. Proper disposal decreases the risk of drug abusers searching through trash to obtain syringes for reuse, which may further spread the HIV virus. When these supplies are not properly handled, trash handlers and others coming in contact with refuse are at risk for injury from lancets and used syringes as well as exposure to blood-borne diseases such as hepatitis and HIV.

The Environmental Protection Agency (EPA) has recently developed guidelines for the proper disposal of home health-care waste. These include recommendations for the disposal of used lancets, syringes, and needles. They are as follows:

1. Do NOT drop a used syringe in the trash can.
2. Needles, syringes, lancets, and other sharp objects should be placed in a hard, plastic or metal container with a screw-on or tightly secured lid. A perfect container is a large, liquid detergent bottle such as Wisk, Liquid All, etc. A coffee can with a small, round hole cut in the lid works well for lancet disposal. If a coffee can is used, the plastic lid should be reinforced with heavy-duty tape. When it is full the container should be sealed tightly and disposed of with the household trash. Local or state regulations may specify a different method of disposal. Check with your local jurisdiction for any specific recommendations.
3. Always select an opaque, puncture-resistant container. Glass or clear plastic containers should NOT be used. Glass may shatter and cause injury. Clear plastic containers allow visibility of contents and may entice a drug abuser.
4. Remind your patients that these containers are NOT recyclable once filled with syringes or lancets. This has been the major problem with this

method in the State of Maryland as reported by the American Diabetes Association. Containers filled with these wastes will contaminate the recycling process due to the metal components.

5. Needles should never be broken or cut off the syringe. Not only is the patient at risk of re-sticking themselves, clipped fragments may become airborne and cause injury. Needles should only be clipped if a device is used which retains the needle in an inaccessible compartment.

The EPA publishes a clear, concise pamphlet which can be distributed to your patients when they purchase syringes or lancets. The pamphlet is titled "Disposal Tips for Home Health Care" and can be obtained, free of charge by writing: RCRA Docket (OS-305) U.S. Environmental Protection Agency
401 M St., S.W.
Washington, D.C. 20460
Or you may call at 1-800-424-9346, Monday through Friday.

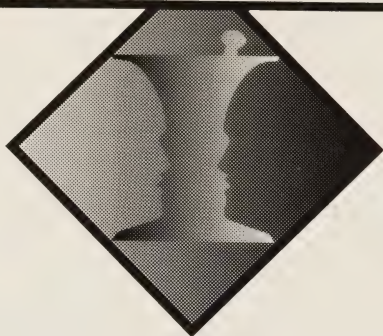
REFERENCE

Patton, A: Your Syringe is Medical Waste. Diabetes Forecast. Oct. 90, 27-29.

Resources

American Diabetes Association	
National Offices	1-800-232-3472
Maryland Affiliate	301-486-5515
Anne Arundel County Chapter	301-859-3390
Frederick County Chapter	1-800-634-4147
Harford County Chapter	301-698-3563
Howard County Chapter	301-836-8407
Lower Shore Chapter	301-371-4332
Upper Shore Chapter	1-800-634-4147
Washington County Chapter	1-800-634-4147
Washington, D.C. Affiliate	301-790-8379
Includes:	202-331-8303
Montgomery County	
Prince Georges County	
Juvenile Diabetes Foundation	
National Offices	1-800-223-1138
Maryland Affiliate	301-356-4555

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National Medication Awareness Test:



How various medications work in the body and how to take them for maximum effectiveness and safety.

Self-Medication Awareness Test:



Stresses that nonprescription medications must be selected and used with the same care as prescription medications.

Managing Your Medicines:



For older patients: focuses on their responsibility in using medications properly and on the pharmacist as an information resource.

Each patient education kit provides the materials needed to successfully publicize and present the program.

Elements include:

1. Videocassette
2. Planning Guide
3. Presentation Instructions

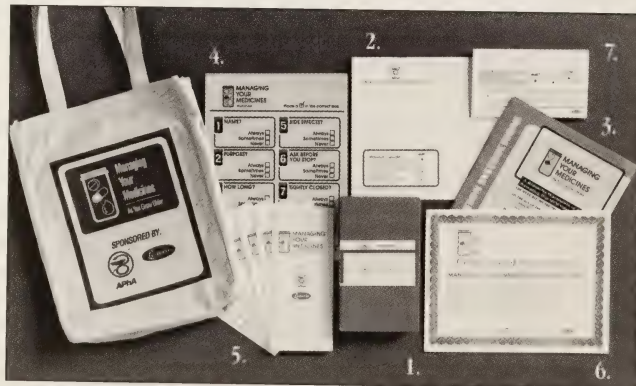
Handouts:

4. Worksheets
5. Medication Records
6. Certificates of Participation

Promotional materials:

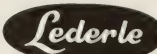
7. Counter display cards, news releases, ad mats

As a practicing pharmacist, you may present to any community organization. At the discretion of the group, your presentation may be open to the public.



Each videocassette is about 20 minutes; generally, presentations include a 5- to 15-minute discussion period following the video.

These three patient education kits have been developed by the American Pharmaceutical Association (APhA) with the cooperation and support of Lederle Laboratories. (The kits also may be purchased directly from the APhA.) Call 1-800-237-APhA.



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6999-1

Prescribing a Blood Glucose Monitor for Your Patient

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Clinical Coordinator
Diabetes Care Management Program
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The tremendous benefits to home blood glucose monitoring has created a market for innovative meters to meet the needs of persons with diabetes. As a result, there are currently machines with many similarities, but just enough differences to leave the consumer confused about product selection. The pharmacist is ideally situated to provide valuable guides to product selection, as well as filling the ongoing needs of monitoring supplies (strips, lancets, alcohol wipes, batteries).

With all the meters available, how does the pharmacist sort through the maze of advertisement, literature, and hearsay? Here are a few basic considerations when prescribing a meter for your patient:

1. Just like medications, there is no one meter which is best for every one. All currently available meters meet recommended standards for accuracy. All meters are within a fair price range and many have rebates, trade-ins, and specials which lower the prices. However, meters vary tremendously in "user friendliness." Some meters require manipula-

tion of strips by wiping or blotting which can be difficult for individuals with poor manual dexterity. Some meters may require exact timing of steps for wiping/blotting and strip insertion. Test each machine yourself. Do not just observe the sales representative quickly and gracefully perform the procedure. Be critical of the procedure. Consider patients with barriers to a particular meter. For example, older patients with arthritis may have difficulty with a Glucometer-3 (R) because the strip must be inserted within 20 seconds after the wiping step. Consider features which are advantages for specific patient populations. For instance, visually impaired patients (which is very common since Diabetes Mellitus is the leading cause of new onset blindness) could benefit from the Accu-chek II Freedom System or the One Touch "Talk and Touch" which are audio systems. These meters talk the patient through the entire testing procedure.

2. The most common source of

error in home blood glucose monitoring is user technique (1, 2). This relates to the first considerations, but also emphasizes the individual must be able to follow the procedure in order to obtain accurate results. The patient must be "teachable" on the selected meter. All meters have exact procedures and deviations have varying effects of the results. Therefore, no matter how accurate the machine is advertised, if the patient is not capable of performing the test properly, the accuracy is lost.

When instructing a patient on meter use, include the following:

- Explain preparation for the test procedure—Inform the patient of all the necessary additional supplies: cotton balls, gauze, etc.
- Explain and show how to obtain a sample—Fingerstick on side or "heel" of the finger
- Demonstrate the test procedure—Watch the individual perform the test to validate comprehension

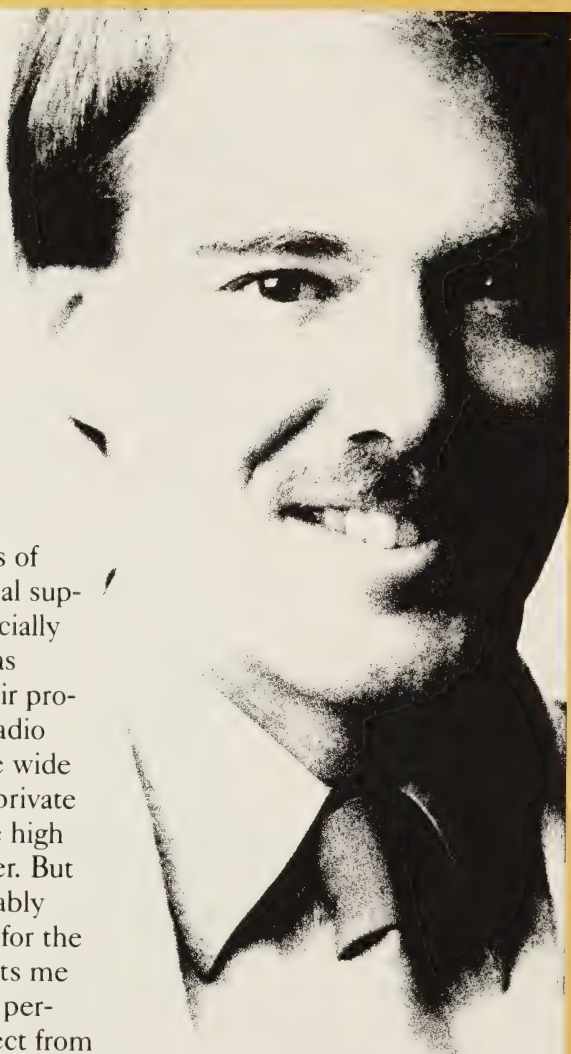
**"Over 3,000
pharmacies
belong to
Valu-Rite.
There must
be a reason.**

In fact, there are lots of reasons. Promotional support for example, especially now that McKesson has added cable TV to their program of circulars and radio spots. Then there's the wide selection of Valu-Rite private label products, and the high profit margins they offer. But most pharmacies probably sign on with Valu-Rite for the same reason I did: it lets me give my customers the personal service they expect from an independent, along with the low prices of a national chain. That's a combination that just can't be beat."

Scott Richards

SCOTT RICKARDS
RICKSAVE DRUG
NAPLES, MAINE

McKesson



MONITORING THE CURRENT METERS

Product/ Manufacturer	Meter Price	Strips Price	Warranty	Range (mg/dl)	Name of Test Strips	Visual Read Capability	Test Time	Memory	Special Features
ACCU-CHECK III Boehringer Mannheim Corp. (800) 858-8072 (24 hours)	\$120-\$130	\$27-\$30 per 50 strips	2 years	20-500	Chemistrip bG	Strip can be read visually	120 seconds	Stores date, time, and 20 test results	Rejects inadequate sample. Must wipe and time. Durable strips. Cues guide user through procedure. Hematocrit range of 25%-60% yields reliable results. Displays date and time. Privacy option.
TRACER II Boehringer Mannheim Corp. (800) 858-8072 (24 hours)	under \$50	\$26-\$27 per 50 strips	2 years	40-400	Tracer bG	Visual verification	120 seconds	Recalls last 10 test results	Must wipe and time. Durable strips. Cues guide user through procedure. Hematocrit range of 35%-55% yields reliable results.
DIASCAN-S Home Diagnostics, Inc. (800) 342-7226	\$85-\$125 minus meter rebate	\$31-\$33 per 50 strips	2 years	10-600	Diascan strips	Strips can be read visually or used to verify meter reading	90 seconds	10 tests	User can smear blood sample onto strip and get clinically acceptable test results. Must wipe and time. Large, easy-to-read display. Privacy option. Results in mg/dl or mmol/L. Temperature compensation range 41°-98°F; adjusts to 73°. Change code to read whole blood or venous blood. No updated information on hematocrit range.
ULTRA (Available Fall '91) Home Diagnostics, Inc. (800) 342-7226	To be deter- mined	To be deter- mined	2 years	0-600	Ultra nonwipe	Can be read visually	45 seconds	2 tests	No timing, wiping, or blotting. Automatic temperature correction. Large, easy-to-read display. Privacy option. Results in mg/dl or mmol/L.
ONE TOUCH II LifeScan Inc. (800) 227-8862 USA (800) 663-5521 Canada	\$125-\$150 minus meter rebate	\$28-\$35 per 50 strips	30-day money- back guarantee; 3-year warranty	0-600	One Touch test strips (foil wrapped or vial packed)	No visual reading	45 seconds	Storage capacity for 250 tests, including date and time of tests	No timing, wiping, or blotting. Signals when meter must be cleaned. Rejects inadequate sample size. Countdown timing. Words appear in English, Spanish, or seven other languages. Hematocrit range of 25%-60% yields reliable results. Communicates with Data Manager unit, most IBM compatible personal computers, Merlin, and Glucocfacts. Privacy option. Results in mg/dl or mmol/L.
COMPANION 2 SENSOR MediSense, Inc. (800) 537-3575 USA (800) 461-8481 Canada	\$130-\$145 minus meter rebate and trade-in	\$32.50- \$34.50 per 50 sensor elec- trodes	4 years	20-600	Pen 2/Com- panion 2 sensor electrodes (foil wrapped)	No visual reading	20 seconds	Recalls last 10 test results	Largest display of readings. No wiping, blotting, or timing. Automatic start. For low-battery reading, send to company (battery life 3-3½ years). Easy strip insertion. No cleaning; blood never enters the sensor. Sensor functions more accurately with hematocrit in 35%-55% range.
PEN 2 SENSOR MediSense, Inc. (800) 537-3575 USA (800) 461-8481 Canada	\$135-\$145 minus meter rebate and trade-in	\$32.50- \$34.50 per 50 sensor elec- trodes	4 years	20-600	Pen 2/Com- panion 2 sensor electrodes (foil wrapped)	No visual reading	20 seconds	Recalls last 10 test results	No wiping, blotting, or timing. Automatic start. For low-battery reading, send to company (battery life 3-3½ years). Easy strip insertion. No cleaning; blood never enters sensor. Sensor functions more accurately with hematocrit in 35%-55% range.
EXACTECH COMPANION MediSense, Inc. (800) 537-3575 USA (800) 461-8481 Canada	\$75-\$80 minus meter rebate and trade-in	\$29-\$31 per 50 strips	4 years	40-450	Exactech test strips (foil wrapped)	No visual reading	30 seconds	Last test reading	One-button operation. No wiping, blotting, or timing.

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Established 1923 Magazines/Books/Newspapers

Product/ Manufacturer	Meter Price	Strips Price	Warranty	Range (mg/dl)	Name of Test Strips	Visual Read Capability	Test Time	Memory	Special Features
EXACTECH PEN MediSense, Inc. (800) 537-3575 USA (800) 461-8481 Canada	\$75-\$80 minus meter rebate and trade-in	\$29-\$31 per 50 strips	4 years	40-450	Exactech test strips (foil wrapped)	No visual reading	30 seconds	Last test reading	One-button operation. No wiping, blotting, or timing.
GLUCOMETER 3 Miles Inc. Diagnostic Division (800) 348-8100	\$40-\$50 minus meter rebate	\$24-\$26 per 50 strips	3 years	20-500	Glucofilm test strips	Visual confidence check up to 240 mg/dl	60 seconds	Recalls last 10 test results	Must wipe and time; durable strip. Option to delete controls and check "paddle" results from memory. Large LED window display. One-button function. Meter functions more accurately with hematocrit in 20%-60% range.
GLUCOMETER M+ Miles Inc. Diagnostic Division (800) 438-8100	\$150-\$160	\$24-\$26 per 50 strips	3 years	20-500	Glucofilm test strips	Visual confidence check up to 240 mg/dl	60 seconds	Stores blood glucose test results with date and time (up to 300 events including blood glucose readings)	Alarm clock. Meter and logbook combined. Allows input of insulin, diet, exercise, and other diabetes-related events. Meter functions more accurately with hematocrit in 20%-60% range. Privacy option. Rebate coupon offer for Glucofacts Data-Link phone modem.
ANSWER Wampole Laboratories (800) 525-6718	\$159-\$179 minus meter rebate	\$28-\$32 per 50 foil- wrapped strips	2 years	40-400	Answer test strips (foil wrapped)	No visual reading	90 seconds	40-test storage capacity	Built-in lancet device. No wiping, blotting, or timing. Automatic check for adequate sample volume. Automatic rejection of used or damaged strip. Automatic temperature correction. Whole blood or plasma reference (corrects for hematocrit). Audio cues with privacy option. Results in mg/dl or mmol/L.

- Demonstrate calibration procedures
- Demonstrate maintenance procedures
- Demonstrate systems check procedures
- Inform the patient about obtaining replacement supplies such as batteries, strips, and lancets
- Emphasize the importance of recording and interpreting results—When should the patient contact the physician?

Proper training is essential in obtaining benefits from home blood glucose monitoring. Poor training may result in noncompliance with home testing or worse yet, inappropriate clinical decisions based on inaccurate data. Patients must perform the test in front of you to clearly demonstrate proficiency in the procedure. In addition, the technique should be periodically reevaluated.

3. Some other areas deserve consideration when selecting a meter. Table 1 (3) shows a comparison of some functional features of currently available meters. Such considerations as costs, memory and "special features" may make selection an easier process. In addition, other factors which may be significant in particular populations include:

- Sample size—The amount of blood necessary to perform the test varies from 7 microlitres for the Glucometer 3 to 50 microlitres for the Accu-check II/III. This may be very important for individuals who have difficulty sticking themselves.
- Interfering substances—some machines are affected

by high levels of ascorbic acid, uric acid or lipids in the blood.

- Hematocrit—Because home blood glucose monitors use whole blood versus plasma, the hematocrit plays a role in the accuracy of results. This is particularly important for populations prone to anemia such as those with chronic renal failure.

Consider developing a form as in Table 2 to complete after evaluating a meter. This form can be used to compare new machines to those already on the market.

Some new developments are focusing on a machine which can detect blood glucose without a fingerstick. The machine, currently in testing by Futrex, Inc., uses a principle

EVALUATION OF BLOOD GLUCOSE MONITOR
MONITOR NAME _____

Available products
Cost of machine
Cost of strips/cartridge
Availability:
Direct
Wholesaler
Rebates/Coupons
Insurance coverage
PROCEDURE:
Ease of use
(Degree of technical skill)
Timing
Blotting/wiping
Sample size
Published data on accuracy
Visual backup
ADVANTAGES:
Marketed advantage
Memory
LIMITATIONS:
Temperature
Humidity
MAINTENANCE:
Battery replacement
Interfering substances
Manufacturer name
Toll-free number

developed in agriculture to determine the ripeness and sugar content of produce. The principle uses near infrared light to pass through the object and record the light transmission. Current research is focused on an accurate, affordable (to compete with existing meters), and painless method to determine blood glucose. No time frame has been released for the availability. Until such time, patients with diabetes are "stuck" with the current technology.

Conclusions:

Home blood glucose monitoring has revolutionized the treatment of diabetes. Ideally everyone with the diagnosis should self monitor. With the variety of meters currently available it is essential to assess the patient for a meter which fits the indi-

vidual's needs. Selecting the meter a patient will use benefits every one: the patient gets better glycemic control, the clinician has useful information to base dosage adjustments, and the pharmacist becomes an integral part of the treatment team by supplying equipment and support to the patient.

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2. Meadows, SK: User errors in blood glucose monitoring. 39th Annual American Diabetes Association Postgraduate Convention Jan. 1991, San Diego, CA.
3. Peragallo-Dittko, V: Buyer's guide to blood glucose meters. *Diabetes Self-Management*. May/June 1991;34-40.

Know The Score: The ADA Position of Community Blood Glucose Screening

Beverly Yachmetz, PharmD, C.D.E.

Effective 1994, the American Diabetes Association (ADA) will no longer recommend blood glucose screening as a means of detecting undiagnosed Diabetes Mellitus (Type II). Reasons cited included lack of standardization of procedure and quality control (1). In addition, one isolated blood glucose reading is highly dependent on food intake and activity for days prior to the sampling. One normal reading may prevent a person at risk for diabetes from proper evaluation and follow-up in the medical system.

However, it is estimated for every individual diagnosed with diabetes, there is one person who has undetected diabetes. It is critical to reach this population. The ADA has developed a risk analysis test to alert individuals to the symptoms and risk for development of Diabetes Mellitus (Type II). A sample is provided below. This test is available through the state ADA affiliate (contact numbers are included in this issue). Administering this test is a painless, effective way to alert your patients to their specific risk for developing diabetes. In addition, it costs a lot less!!

REFERENCES

1. American Diabetes Association, Newsletter, 9/91:1
2. American Diabetes Association, Diabetes take the test. Know the score. 1989.

Are you at risk for diabetes? Could you already have diabetes and not know it?

Take the Test. Know the Score.

Write in the points next to each statement that is *true* for you.
If a statement is *not true* for you, put a zero.
Then add up your total score.

1. I have been experiencing one or more of the following symptoms on a regular basis:
 - excessive thirst Yes 3 _____
 - frequent urination Yes 3 _____
 - extreme fatigue Yes 1 _____
 - unexplained weight loss Yes 3 _____
 - blurry vision from time to time Yes 2 _____
 2. I am over 30 years old. Yes 1 _____
 3. My weight is equal to or above that listed in the chart. Yes 2 _____
 4. I am a woman who has had more than one baby weighing over 9 lbs. at birth. Yes 2 _____
 5. I am of Native American Indian descent. Yes 1 _____
 6. I am of Hispanic or Black descent. Yes 1 _____
 7. I have a parent with diabetes. Yes 1 _____
 8. I have a brother or sister with diabetes. Yes 2 _____
- Total** _____

Scoring 3-5 points:

If you scored 3-5 points, you probably are at low risk for diabetes. But don't just forget about it. Especially if you're over 40, overweight, or of Black, Hispanic, or Native American Indian descent.

What to do about it:

Be sure you know the symptoms of diabetes. If you experience any of them, contact your doctor for further testing.

Scoring over 5 points:

If you scored over 5 points, you may be at high risk for diabetes. You even may already have diabetes.

What to do about it:

See your doctor promptly. Find out if you have diabetes. Even if you don't have diabetes, know the symptoms. If you experience any of them in the future, you should see your doctor immediately.

The American Diabetes Association urges all pregnant women to be tested for diabetes between the 24th-28th weeks of pregnancy.

This test is meant to educate and make you aware of the serious risks of diabetes. Only a medical doctor can determine if you do have diabetes.

Weight Chart

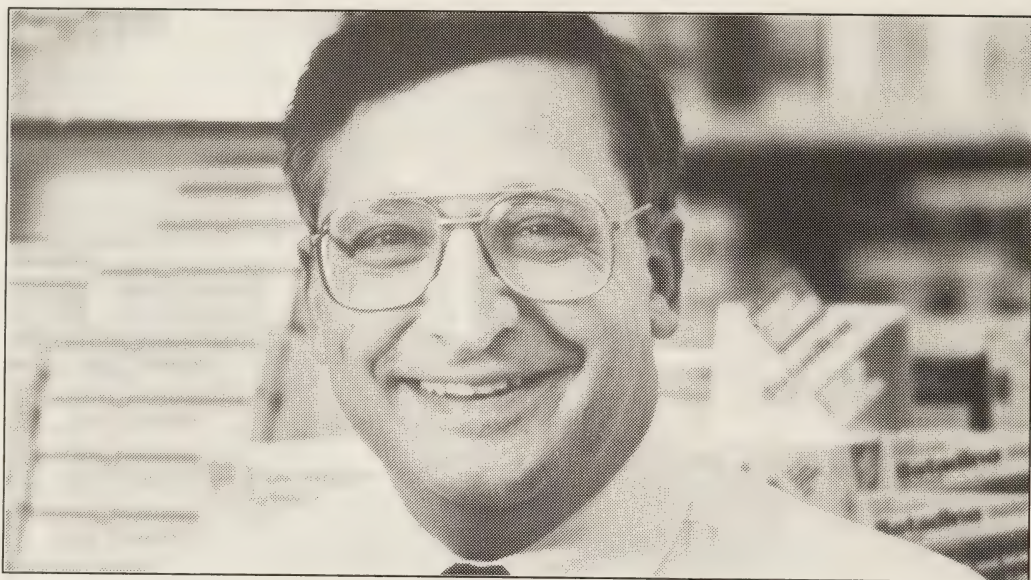
(shows 20% over maximum weights)

Height (without shoes)		Weight in Pounds (without clothing)	
		Women	Men
Feet	Inches		
4	9	-----127	
4	10	-----131	
4	11	-----134	
5	0	-----138	
5	1	-----142	-----146
5	2	-----146	-----151
5	3	-----151	-----155
5	4	-----157	-----158
5	5	-----162	-----163
5	6	-----167	-----168
5	7	-----172	-----174
5	8	-----176	-----179
5	9	-----181	-----184
5	10	-----186	-----190
5	11	-----196	
6	0	-----202	
6	1	-----208	
6	2	-----214	
6	3	-----220	

These charts show weights that are 20% heavier than the maximum recommended for both men and women with a medium frame. If your weight is at or above the amount listed for your height, you may be at risk for developing diabetes.

Check with your local American Diabetes Association (ADA) chapter or affiliate for more information about diabetes, healthy eating, and exercise. (Numbers are listed in the White pages of the phone book.)

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Insulin Transfer in Diabetic Patients

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and
Toxicology;
Chairman, Department of Clinical
Pharmacy
Ohio Northern University
Ada, OH

Advances in diabetes control are occurring at record speed. Pharmacists may understandably be confused by claims that accompany activity in this area, and be apprehensive about what to accept as fact. Paramount in contemporary therapeutics are two critical considerations:

- Insulin products within formulation types (i.e., Regular, Lente, NPH, and 70/30 mixtures) are identical to each other chemically, and in clinical response; and

- Diabetic patients can be safely transferred from one brand of insulin to another without affecting a clinically significant change in metabolic control. Supporting studies have confirmed therapeutic equivalence in healthy individuals, and transferability in diabetic patients.

Background

With discovery of insulin in 1921 in Canada, there has been intense emphasis worldwide to further refine it to improve treatment alternatives for patients with diabetes mellitus. The most significant development occurred within the past decade when Danish researchers learned how to alter the structure of porcine insulin to create the world's first human insulin. This insulin mimicked the endogenous hormone, and was marketed in Europe in 1982.

Meanwhile, closer to home, a

fledgling high-tech venture company, Genentech, had discovered a means to produce human insulin through genetic engineering of the gram-negative bacterium *Escherichia coli*. New vistas were suddenly opened with means for synthesizing drugs that were previously unavailable to the pharmaceutical industry.

This technology has most recently been extended to an even more refined method of insulin production. The innovative process involves recombinant DNA (rDNA) technology using baker's yeast as host cells. Baker's yeast has a long history of use in the food industry. In the new process, a segment of plasmid DNA is altered to code for the human insulin precursor. This is inserted into *Saccharomyces cerevisiae* (baker's yeast) by a process called transformation, and will be passed along to all succeeding generations. The product of secretion is termed "miniproinsulin" because it conveniently contains a shorter c peptide chain than endogenous insulin, or proinsulin produced by *E. coli*. The C peptide is easily removed with the enzyme trypsin, resulting in human insulin that requires no further processing or chemical modification.¹

This latest production method is the most sophisticated means yet in the quest to provide diabetic patients with the ultimate therapy to treat

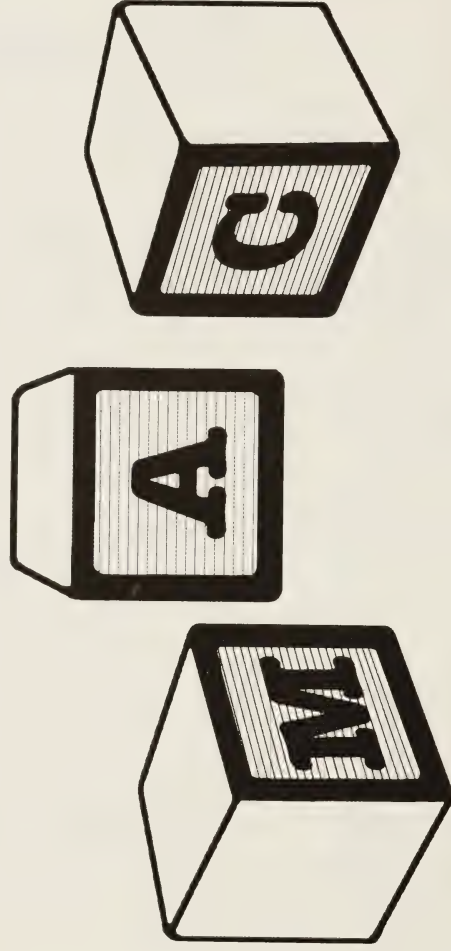
their disease. It affords limitless quantities of insulin that is structurally and clinically identical to endogenous human insulin. New to America, human insulin synthesized by baker's yeast has been available in Europe since 1988, and is used in 70 countries worldwide.

Transfer of Patients From Insulin Of One Source To Another

The new insulin produced by baker's yeast replaces its semisynthetic precursor. To confirm their equivalence, a multicenter, randomized, double-blind parallel-group, 12-month study with 65 diabetic patients was undertaken. Subjects received either the new rDNA product, or the semisynthetic human insulin product. Treatment included Regular, Lente, and NPH dosage forms. Blood samples were obtained and analyzed for glycosylated hemoglobin A_{1C}, and human insulin antibodies.²

Glycosylated hemoglobin remained stable throughout the 12-

Editor's Note: MPhA members are encouraged to post the poster appearing on the next two pages in their pharmacies. This poster is provided by MPhA in assistance to the Department of Health and Mental Hygiene's "Access to Care" program.



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Maryland Access to Care (MAC) is a new program for people who get Medical Assistance.

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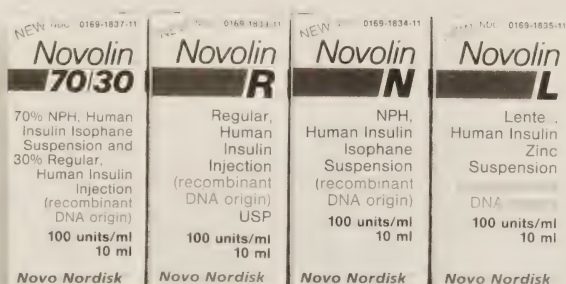
- **Give you medical care**
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- **Keep your medical records**

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If you need the names of doctors or clinics near you, or if you have questions, call **225-5800** (in Baltimore) or **1-800-492-5231**.

MAC means better health care for you
and your family!

*This message brought to you by your pharmacist and the
Maryland Pharmacists Association.*



Novo Nordisk Pharmaceuticals Inc. will be introducing NOVOLIN_R human insulin (rDNA origin) this fall. This product will be available as existing inventories of NOVOLIN_R human insulin (semi-synthetic) are depleted.

month study period, as shown in Figure 1. There were no treatment-related statistically or clinically significant differences between patient groups in parameters of transferability including safety.

Four other studies compared semisynthetic human insulin with human insulin synthesized by *E. coli*, and human insulin produced by baker's yeast. Each was a double-blind, three-way crossover design that evaluated Regular, NPH, Lente, or premixed 70/30 insulin. In each protocol, 15 healthy volunteers received a single uniform dose of each product in random order at one week intervals. Blood samples were taken for analysis of insulin and se-

rum glucose before, and for 12 hours (Regular human insulin study) and 24 hours (other studies) after injection. Study outcomes confirmed that there was no clinically significant difference in the glucose lowering pharmacodynamic effects of single doses of any human insulin product, regardless of source.^{3,4} These data support that patients can be transferred from one human insulin product to the other, dose-for-dose. Of course, it is standard practice to transfer patients under medical supervision.

All Things Considered!

Suggestions that human insulins

derived from variant sources differ in their clinical response counter the data from controlled scientific investigation that document their similarities. There is only one human insulin; this is assured by the single monograph published for human insulin in the USP XXII/NF XVII.

Pharmacists may be familiar with an FDA warning against switching insulins. This warning was published a decade ago, before introduction of human insulin in the U.S. It advised against transferring patients from insulins of different animal sources (e.g., pork or beef), different degrees of purity (which were common at that time), and different strengths (e.g., U40 and U80). Today, when contemplating human insulin brands, pharmacists should consider the latest data available on the clinical equivalence of rDNA human insulin products.

Pharmacists make many routine cost-savings decisions in the daily management of their pharmacies, regardless of whether these are community-based, or part of a hospital or other managed-care facility such as a HMO. When significant cost savings are available, while providing clinically equivalent products, this assures a healthy financial picture for both the patient and the health-care industry.

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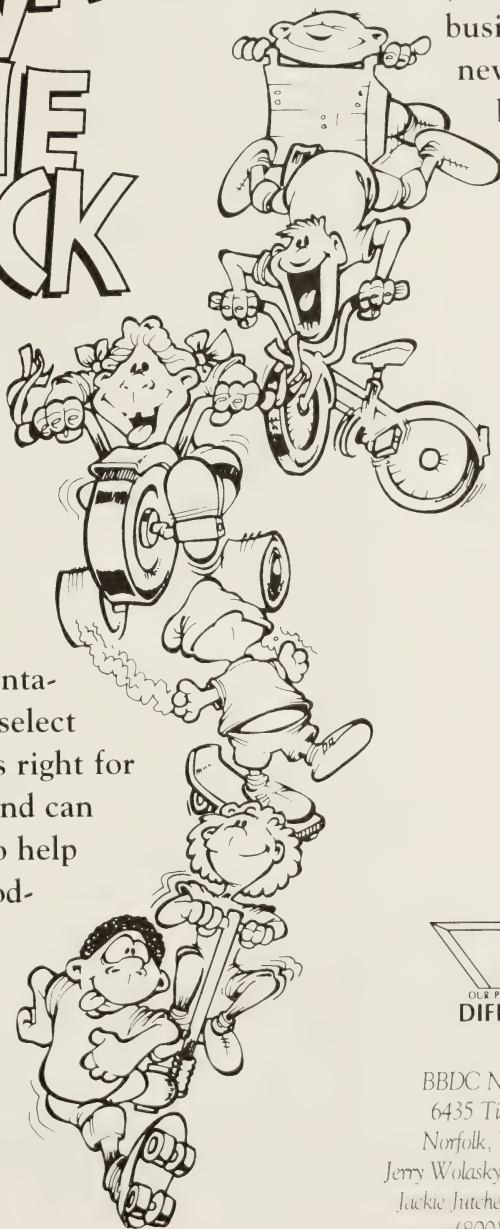
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Pharmacists' Attitudes Toward Managed Health Care

Today, with six out of 10 pharmacies affiliated with a managed health care organization, pharmacists strongly agree that the resulting paperwork is a major source of distress, according to an independent, nationwide survey commissioned by Schering Laboratories. However, pharmacists are divided on the relative benefits and drawbacks of third-party affiliations, the study showed.

"Pharmacists have been complaining about third-party programs for a long time," said Dr. Jack Robbins, director of pharmacy affairs for Schering Laboratories. "In the 1981 Schering Report, pharmacists identified third-party programs as their number one problem, citing low reimbursement, slow payment, excessive paperwork and the fact that they had no voice in setting fees."

Results of the new Schering Report indicate that managed health care is still a vexing issue today, "if anything, even more so because it carries the potential to radically alter the profession of pharmacy as we know it," he added.

Schering Report XIII, "Managed Health Care: A Benefit and a Burden," was based on personal interviews with 500 pharmacists across the country. Designed to explore the impact of managed health care programs on pharmacies today, the study asked: What are pharmacists' attitudes toward this growing phenomenon? How is managed health care affecting everyday pharmacy practices? What is the future likely to bring?

Examining the report's findings, what has changed is a growing recognition by pharmacists that ignoring third-party-related issues doesn't work. But there are encouraging signs that pharmacists are beginning

to learn to deal with them, and even profit from them.

Driving the managed health care issue are the sobering statistics on the nation's rising health care costs, which rose 11.9 percent in 1990, according to the U.S. Department of Commerce. Employee medical costs increased to \$3,217 per worker, accounting for 26 percent of the average company's net earnings. At the current rate, traditional medical costs are projected to reach \$22,000 per employee by year 2000.

As managed health care plays a greater role in the American health care system, pharmacists expect to be under increasing pressure to find time during an already burdened workday to handle the mounting paperwork that these programs will no doubt demand in the future, the study revealed.

Given pharmacists' strong feelings about third-party paperwork, the study sought to determine what percentage of prescriptions are co-pay or third-party pay. According to the pharmacists surveyed, the answer fell just short of half, at 46 percent and there was surprisingly little difference among those who were affiliated with a Home Maintenance Organization (HMO) and those who were not.

The study reported that nine out of 10 pharmacists expect an increased percentage of co-pay and third-party-pay prescriptions in the average pharmacy. Fifty-seven percent expect a "substantial" increase and 32 percent said the percentage will increase "somewhat."

With third-party prescriptions expected to put ever greater demands on their already limited time, pharmacists might be expected to cut back on traditional activities to ac-

commodate growing demands of third-party paperwork.

But this is apparently not so, according to the Schering Report.

Nearly half of the pharmacists (45 percent) predicted that they would be devoting more time to third-party payments, followed by counseling patients on prescriptions (43 percent), advising on over-the-counter drugs (34 percent), discussions with physicians (29 percent), keeping up with the "literature" (28 percent) and advising customers on non-drug products (25 percent).

It's clear from the data that dealing with third-party payments is on the minds of most pharmacists. Representing almost half of their present business, these are consuming what they already feel is too much of their worktime, and they fear it will claim an even larger share in the future.

As pharmacists look ahead to a future buried in third-party paperwork, are they optimistic or pessimistic about the future of pharmacy? A strong majority of pharmacists (72 percent) are optimistic and only 28 percent pessimistic.

Analyzing the pessimists' responses, more of them practice in independent pharmacies (42 percent) than chains (22 percent), and pharmacists over age 35 are more pessimistic (31 percent) than younger pharmacists (20 percent).

Schering Report XIII also looked at pharmacists' satisfaction with the pharmaceutical sales representatives (PSRs) who call on them. About one in four of the pharmacists (27 percent) was completely satisfied with the relationship, 60 percent somewhat satisfied and 1 percent completely dissatisfied.

On average, pharmacists talk to

Continued on page 24

AIM HIGH



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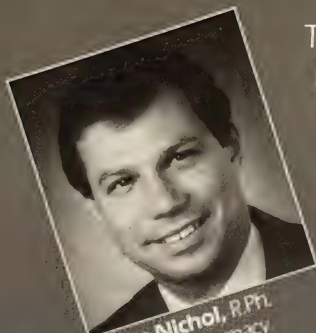
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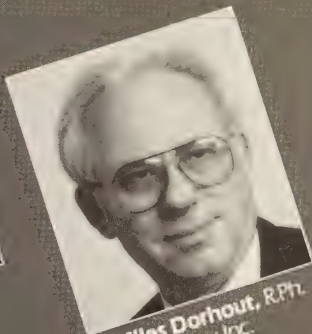
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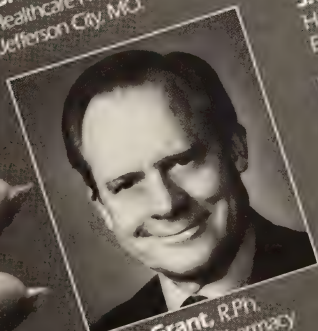
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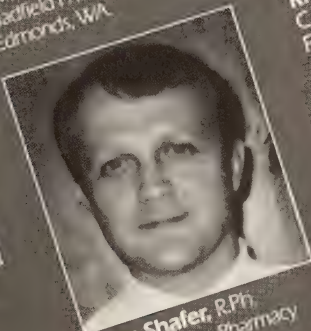
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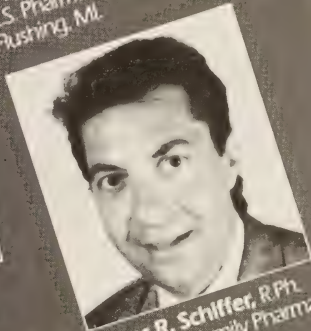
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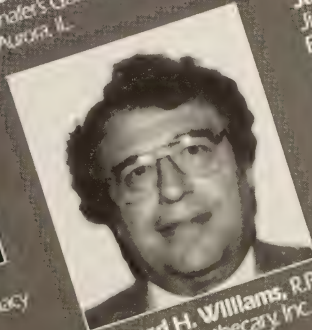
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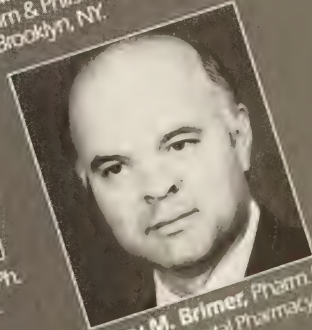
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3.6 PSRs per week, according to the study. Pharmacists in independent pharmacies reported seeing a much higher number, 5.6 "reps" per week.

Do pharmacists perceive all PSRs as virtually equivalent, irrespective of their pharmaceutical company? On this issue, the pharmacists split pretty much down the middle.

Differences among PSRs are mostly viewed as being on the positive side; that is, their degree of knowledge, or how informative or personable and friendly they are. Some pharmacists, however, see the main differences among PSRs in their degree of pushiness.

Noting that half of the pharmacists found differences among various sales reps, the study asked them to name the pharmaceutical companies with the "best" PSRs. Pharmacists named these top 10 companies: Eli Lilly, Merck, Upjohn, Glaxo, Schering-Plough, Searle, Abbott Laboratories, Bristol-Myers Squibb, Hoechst-Roussel and SmithKline Beecham.

The Schering Report also rated the professional relationship between pharmacists and the "typical physician." Twenty-eight percent of pharmacists are satisfied with the relationship, while 10 percent are somewhat satisfied and 2 percent are completely dissatisfied.

While most contacts with PSRs occur face to face, with physicians it's phone to phone, the study revealed. In a typical day, pharmacists average 21.1 phone calls to physicians' offices and receive 24.7 calls from doctors' offices.

"By physicians' offices, of course, pharmacists mean the physician or the physician's staff, as only one phone call in four involves the pharmacist speaking directly to the physician," he said. "Fully two-thirds of the pharmacists (66 percent) said they would prefer to speak directly to the physician more often than they do now."

Just what would they talk about? Probably about what pharmacists feel physicians depend on them for—issues related to pharmacist—

patient communications and pharmacist-physician contacts, for example.

In the pharmacist-patient category, pharmacists feel that doctors depend on them to give patients information on dosage (20 percent) and on potential side effects of medications (9 percent). Pharmacists (19 percent) also feel that doctors expect pharmacists to maintain patient profiles.

So what is the future of the pharmacist-physician relationship? About half of the pharmacists (52 percent) expect that over the next

five years the relationship will remain as it is now. Of the remainder, 40 percent anticipate an improvement and only 8 percent foresee a deterioration.

Pharmacists who expect deterioration blame a range of factors including fax machines, doctors turning over more of their work to assistants, and the intervention of insurance companies.

The owner of an Oklahoma independent pharmacy explained: "Because insurance companies are pushing people to go to specific pharmacies, doctors and pharma-



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Management and
Circulation**
(Required by 39 U.S.C. 3685)

1A. Title of Publication MARYLAND PHARMACIST		1B. PUBLICATION NO. 0 0 2 5 4 3 4 7		2. Date of Filing 3B. Annual Subscription Price \$10
3. Frequency of Issue Monthly		3A. No. of Issues Published Annually 12		3B. Annual Subscription Price \$10
4. Complete Mailing Address of Known Office of Publication (Street, City, County, State and ZIP+4 Code) (Not printers) 650 W. Lombard Street, Baltimore, Maryland 21201				
5. Complete Mailing Address of the Headquarters or General Business Office of the Publisher (Not printer) 650 W. Lombard Street, Baltimore, Maryland 21201				
6. Full Names and Complete Mailing Address of Publisher, Editor, and Managing Editor (This item MUST NOT be blank) Publisher (Name and Complete Mailing Address) Maryland Pharmacists Association 650 W. Lombard Street, Baltimore, Maryland 21201 Editor (Name and Complete Mailing Address) David Miller 650 W. Lombard Street, Baltimore, Maryland 21201 Managing Editor (Name and Complete Mailing Address) Same				
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10. Extent and Nature of Circulation (See instructions on reverse side)		Average No. Copies Each Issue During Preceding 12 Months		Actual No. Copies of Single Issue Published Nearest to Filing Date
A. Total No. Copies (Net Press Run)		1485		1595
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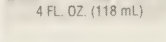
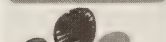
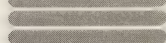
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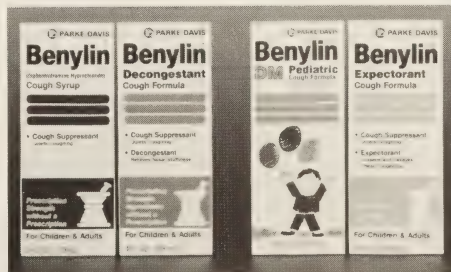
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cists will have less interaction as a result."

Probing further into the future of the pharmacy profession, the Schering Report focused on what many describe as a big third-party wave—in the form of managed health care—rolling inexorably toward the pharmacist's doorstep. To what extent are pharmacists currently involved in these programs? How do they feel about them, and what are their expectations for a future that involves these plans exercising greater influence?

Asked if their pharmacy is "officially associated with any managed health care organizations," six out of 10 (59 percent) said yes. The highest rate of association was among chain pharmacies (72 percent), with supermarket pharmacies the runner-up (63 percent) and independents third (53 percent).

When pharmacists, associated or not, were asked if they saw any "major advantages" or "major disadvantages" from managed health care, exactly half (50 percent) were unable to cite any major advantage. Among pharmacists who said the plans did offer some advantages, 12 percent felt they helped increase sales volume and, therefore, helped the pharmacy make more money.

A second advantage cited was that these plans help to reduce costs to the patient. A pharmacist in a supermarket pharmacy in Utah associated with a managed health care plan pointed out that "besides being more economical for the consumer, it helps us build a steady clientele and makes it easier to monitor profiles."

When interviewers asked pharmacists to list some major disadvantages that might result from managed health care, almost half cited the impact on the economics of running a pharmacy. Nineteen percent cited decreased profits and 12 percent felt that under managed health care pharmacists would be controlled and third parties would dictate prescription prices. Only one in 10 (10 percent) saw no disadvantages.

Still another fear voiced by pharmacists is 'slow payment.' This was

mentioned by only 7 percent of those not affiliated with a plan, but by 16 percent of those who were. To them, slow payment is apparently not merely speculation but a reality.

Aside from dollars-and-cents disadvantages, pharmacists cited three other areas of concern: "third parties restrict us, tell us how to practice our profession" (18 percent); "increased paperwork" (16 percent); and "patients have no freedom of choice" (13 percent). Several independent pharmacists pointed out that health care plans favor larger pharmacies such as chains, thereby locking out independents.

The Schering Report noted that managed health care will continue to grow. Using its growth to date as a yardstick, the study asked whether pharmacists feel it has (1) helped them improve the quality of service provided to patients, (2) caused a decline in quality or (3) had no effect either way?

Just over half (53 percent) perceived no effect. A little over a third (35 percent) noted a decline, and only 12 percent felt that managed health care helped improve the quality of service to their patients.

Does affiliation with an HMO influence a pharmacist's judgment of managed health care? Among those with no HMO connection, twice as many see a decline in service as see an improvement (29 percent versus 15 percent). But that rate skyrockets to three-and-one-half-to-one (38 percent versus 11 percent) among those having first-hand experience with an HMO.

Pharmacists who have HMO contracts—and are in the best position to know—feel that managed health care causes a decline in the quality of services provided to patients.

Two reasons were cited most often for the decline in service: the fact that pharmacists must work with a restrictive formulary and are forced to use specific drugs, and, once again, the increased volume of paperwork.

If pharmacists see managed health care as detrimental for patients, do they also consider it bad for pharma-

cists? Apparently not. Fifty percent said their business had benefited and only 13 percent said it had been hurt. The remaining 37 percent saw no effect either way.

How do pharmacists assess the impact of managed health care on their profession?

Not too favorably. Pharmacists registered a strong negative vote (53 percent). Only 27 percent saw a positive outcome and 20 percent were neutral. The negative majority carried the day with independent, chain and supermarket pharmacists, and this feeling was shared equally by both pharmacists with and those without an HMO affiliation.

For the pharmacy profession too, the future looks overcast when it comes to the influence of managed health care, the Schering Report observed.

Despite gloomy predictions from some doomsayers, pharmacists are beginning to confront the managed health care question squarely and to recognize that an effective defense must include collective action.

The Schering Report urged pharmacists to get involved with the "excellent" professional associations that represent them at national, state and local levels. Pharmacists can no longer afford just to react to health care policies that affect them but have been formulated with almost no significant input from the pharmacy community. The voice of pharmacy must be heard earlier and louder in the policy-making process.

The Schering Report concluded: Pharmacists should regard managed health care—and its potential to overpower them with paperwork and shackle them with restrictive conditions—as just one more problem to overcome. In the long run, they will turn this into an opportunity to serve patients even better as their pharmaceutical needs become ever more complex with new breakthroughs in medical therapies.

A booklet summarizing the Schering study is available by writing: Pharmacy Affairs Department, Schering Laboratories, Kenilworth, N.J. 07033.

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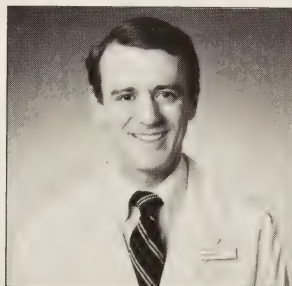
Important figures in diabetes care



Diabetes is the **No. 7** cause
of death in the US¹



Diabetes is the **No. 1** cause of new
blindness in persons aged 20-74¹



Pharmacists see patients with diabetes
5 times more often than do physicians.
These customers spend 3 to 8 times more
annually in the pharmacy than persons
without diabetes.²



Global Excellence in Diabetes Care

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Your Lilly sales representative will visit you soon with
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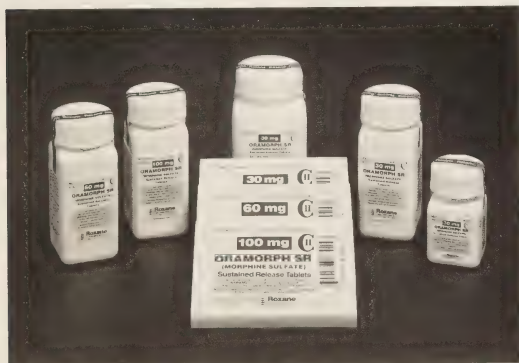
1. *Diabetes Surveillance, 1980-1987*. Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes*. Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.



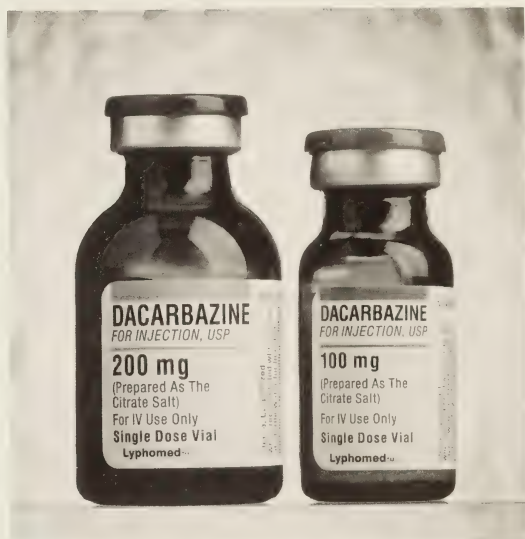
Roxane Laboratories has announced the first and only oral solution of lorazepam. Called Lorazepam Intensol, the solution is packaged in bottles of 30mL with tamper evident closures and calibrated droppers. The product has a concentration of 2 mg/mL.



Another prescription product moves over-the-counter! DuoFilm wart remover products will include a liquid, a gel and a patch formulation. DuoPlant, the gel formulation designed for plantar warts, will be the first OTC product indicated for this type of affliction.



Roxane Laboratories has announced the introduction of new Oramorph SR, a morphine sulfate sustained release tablet preparation. The product is designed to provide 12-hour relief from cancer pain. Adria Laboratories will co-promote Oramorph SR.



Lyphomed has unveiled its latest entry in its oncolytic line, dacarbazine for injection. The product is offered in both 100mg and 200mg sizes to meet patients' dosing requirements and features bold labeling and colored caps to distinguish sizes and clearly identify the product.

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Continuing Education Quiz

The Maryland Pharmacist

NOVEMBER 1991

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by March 31, 1992. A continuing education certificate for one contact credit will be mailed to you within 30 days. Please type or print clearly.

Name _____

Social Security Number _____

Address _____

City/State/Zip _____

Is this program used to meet your mandatory CE? ☐ Yes ☐ No

Did this article achieve its stated objectives? ☐ Yes ☐ No

How long did it take you to complete the program? _____ minutes

The questions for this month's continuing education quiz are drawn from the articles on diabetes care throughout the journal.

1. The most recent technology to produce human insulin is:
 - a. modification of the porcine insulin molecule.
 - b. genetic engineering of *E. coli*.
 - c. recombinant DNA involving bakers' yeast cells.
 - d. none of the above.
2. Studies indicate the parameters which remain stable during comparisons between human insulins are:
 - a. high and low sugar reactions.
 - b. Insulin and serum glucose levels.
 - c. glycosylated hemoglobin A1c and proinsulin.
 - d. all of the above.
3. FDA warnings about switching insulin address:
 - a. different source insulins.
 - b. different degrees of purity.
 - c. different strengths.
 - d. all of the above.
4. The best way to determine "user friendliness" of a blood glucose monitor is to:
 - a. read the accompanying literature.
 - b. watch a demonstration.
 - c. view the available video tape.
 - d. preform the test yourself.
5. When recommending a meter for your patient, the most important consideration is:
 - a. the individual's ability to use and maintain the specific machine.
 - b. the cost.
 - c. the color.
 - d. the components included in the kit.
6. Training an individual to operate a specific blood glucose monitor includes:
 - a. test procedures.
 - b. maintenance procedure.
 - c. recording the results.
 - d. all of the above.
7. Those who benefit from home blood glucose monitoring include:
 - a. the individual patient.
 - b. the treating clinician.
 - c. the pharmacist.
 - d. all of the above.
8. Guidelines for syringe/lancet disposal have been developed by:
 - a. FDA
 - b. USDA
 - c. DEA
 - d. EPA
9. An ideal container for disposal of lancets is:
 - a. a glass jar with a lid.
 - b. a trash can.
 - c. a plastic deli container.
 - d. a coffee can.
10. The ADA will no longer recommend fingerstick screening because:
 - a. costs are too high.
 - b. individuals do not like to get their finger stuck.
 - c. an isolated reading is too dependent on other factors.
 - d. high risk of spreading blood-borne diseases.

Classified

"Rx" LICENSE PLATES are still available through the Association. When you receive your license renewal form, contact Mary Ann at the Association (727-0746) for details. The plates say "Maryland Pharmacists Association" in addition to "Rx" and the number. This offer is open to members and their families only.

THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION (organized in 1926) meets every third Wednesday of the month at Horn and Horn Smorgasboard on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (301) 358-7036.

FREE CLASSIFIEDS. MPhA members may place a classified ad at no cost in the journal. Send your typewritten ad to 650 West Lombard St., Baltimore, Maryland 21201.

FOR RENT St. Thomas, U.S. Virgin Islands Condominium (weekly rental). Two bedrooms, two baths, overlooks the Caribbean on the beach. Ideal for two couples or family. Please contact: Dr. Steven J. Berlin, (301) 247-4770, evenings: (301) 252-7508.

FOR RENT: St. John, USVI, Gallow's Point—Oceanfront 1 bedroom condo with pool and daily maid service. Low airfare available. 10% discount to pharmacists. Call Richard Matheny (301) 948-8547.

FDA HOTLINE FOR AIDS information is 800-432-AIDS.

FOR RENT: St. Thomas, USVI, Mahogany Run—Oceanfront 2 bedroom, 2 bath condo. Perfect for 2 couples or family. Golf, tennis and pool. 10% discount to pharmacists. Low airfare available. Call Richard Matheny (301) 948-8547.

PHARMACIST WANTED for full or part-time position available in a busy growing pharmacy in Lutherville. Tired of frustration, long hours, slow computers, lack of help? Good benefits, vacation, and profit sharing in an exceptional working environment. The right applicant will be a motivated, people oriented person who enjoys working with the public. Call Roger Heer at Valley Pharmacy, (301) 252-4433.

155 PHARMACISTS AVAILABLE for retail, hospital and institutional pharmacy positions. We're ready and able to meet your needs for holiday, vacation, illness, or any time you need pharmacy coverage. Need a pharmacist? Call (301) 659-STAT.

THINKING OF RETIRING? Motivated, energetic pharmacist looking to buy a profitable retail pharmacy. Some owner financing is desired. Please contact through the MPhA office at (301) 727-0746.

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PHARMACISTS REHABILITATION COMMITTEE HOTLINE is (301) 727-0746.

PHARMACIST WANTED for permanent part-time work, one or two days a week. No evenings or Sundays. Located near Denton on the Eastern Shore. If interested, call MPhA at (800) 833-7587.

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PHARMACIST AVAILABLE for full or part time position in retail pharmacy or pharmacy administration. Preferably in Frederick County or Western Maryland area. Call (301) 845-6040.

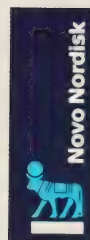
PHARMACY FOR SALE This independent pharmacy is located in a small, lovely bayside fishing and farming community, where it has operated successfully for more than 30 years. The present owner is the original founder looking to retire. Sales price is \$123,000. For more information, contact Sandy Levine at (301) 428-8192.

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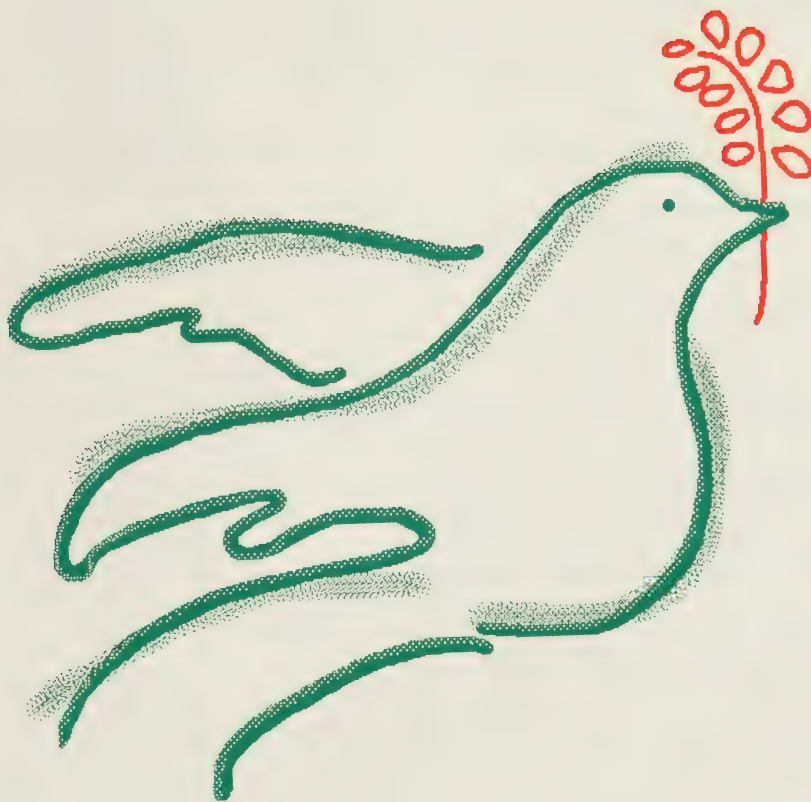
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The Maryland Pharmacist

VOL. 67

December, 1991

No. 12



*May Your Holiday Season Be
Filled with Peace and Hope*

The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association
650 West Lombard Street, Baltimore, Maryland 21201-1572

December 1991

Volume 67

Number 12

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The Maryland Pharmacist, ISSN 0025-4347, is published monthly by the Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572. Annual Subscription - United States, \$10 a year. Single copies, \$1.50. Members of the Maryland Pharmacists Association receive *The Maryland Pharmacist* as part of their annual membership dues. Entered as second class matter at Baltimore, Maryland and additional mailing offices. Postmaster: send address changes to *The Maryland Pharmacist*, 650 West Lombard Street, Baltimore, MD 21201-1572.

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Consumer Access to Pharmacy Services

President Ilene Zuckerman, Pharm.D.

Consumer access... freedom of choice... open networks...

These are all buzzwords for one of the Association's critical lobbying issues in Annapolis this year. Why? Obviously pharmacists want the opportunity to provide pharmacy services to subscribers of prepaid prescription plans. We don't want to be "closed out" from business or practice opportunities.

Consumer access legislation would allow any pharmacy -- regardless of size, ownership status, or number of store locations -- the same opportunity to evaluate any contract or reimbursement terms offered by any HMO. Consumer access legislation does not require any HMO to accept the terms or reimbursement set by the pharmacy, but rather allows the HMO to set the terms of reimbursement.

The HMO industry and other opponents of consumer access legislation may argue that such legislation is self-serving to pharmacists, and that a restricted network has economic advantages, due to large volume purchase discounts available to the network pharmacies. The HMO industry is fearful that, by opening the networks, costs, reimbursements, and therefore premiums will increase. However, consumer access legislation is actually pro-competitive, by allowing *all* pharmacies to inject price competition, which can result in more favorable terms for the HMO.

But what about quality of care? Opponents of consumer access legislation argue that quality assurance programs, such as drug utilization review, are easier to administer when there are a limited number of pharmacies whose records must be reviewed. However, with currently available technology, it is possible to

manage drug utilization programs with multiple pharmacies in the network. This is exemplified by the Maryland DUR Program operated by MPhA for the Maryland Medical Assistance Program.

Opponents of consumer access legislation argue that patients exert their "freedom of choice" when they sign up for a particular HMO program. In reality, consumers choose their health care plan with little knowledge or understanding about the intricacies of the plan; the consumer may not even understand how to evaluate a prescription benefit program.

When speaking or writing to your legislators and patients about the consumer access issue, please remind them:

We are not asking for legislation to make the HMO industry set rates and reimbursement terms acceptable to all pharmacies.

We are not asking for guaranteed business.

We are asking for the opportunity to receive, evaluate and decide whether to participate in an HMO's pharmacy benefit program.

Consumer access legislation will preserve existing patient pharmacist relationships established before the patient joined the HMO.

Don't our patients deserve this legislation?

Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

Advising Patients on Urinary Tract Infections

by Thomas A. Gossel, R.Ph.,
Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to discuss the etiology and treatment of urinary tract infections, and present information that can be passed along to interested consumers.

Objectives

At the conclusion of this lesson, participants should be able to:

1. select common etiologic causes and specific terminology that pertain to urinary tract infections;



Gossel



Wuest

2. choose the therapeutic agents used to treat urinary tract infections, and their mechanism of action, adverse effects, and therapeutic applications; and

3. choose from a list, appropriate advice to convey to patients with urinary tract infections to assure they receive maximum therapeutic benefit from their treatment.

Urinary tract infections (UTIs) are reported to affect upwards of 10 per-

cent of the population, depending on the age of the patient. Infections of the genitourinary tract are second only to those of the respiratory tract in frequency during childhood. They are said to account for five million physician visits annually in the U.S. Approximately 20 percent of all antibiotic prescriptions are issued for treating UTIs.

Background

Urinary tract infections are common in both young males and females under one year of age, but thereafter are more prevalent in females. This prevalence continues throughout life with incidence increasing with advancing age, probably due to decreasing ability to manufacture antibodies in response to infection. The incidence of bladder, urethral and kidney disease increases in men as they reach their 60s. At this age, the incidence of these diseases is similar in men and women.

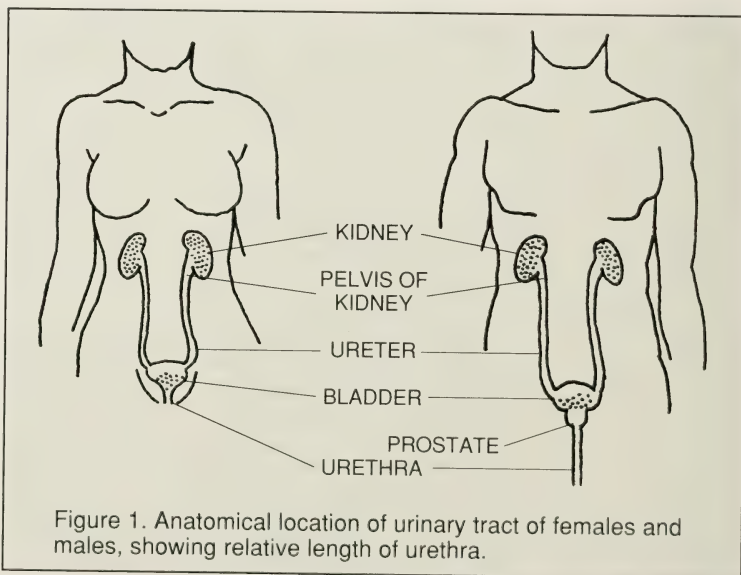


Figure 1. Anatomical location of urinary tract of females and males, showing relative length of urethra.

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SEARLE

Urinary tract infections are reportedly the most common type of hospital-acquired infection. The incidence may include as many as 30 percent of inpatients, depending on their overall health, and/or whether instrumentation (catheterization, cystoscopy) was employed. Improper technique in catheterization is an important cause of hospital-acquired UTIs. Infective organisms can be introduced with the catheter during insertion or migrate along an indwelling catheter.

Most bacteria that invade the urinary tract are normal inhabitants of the lower GI tract. This may explain, in part, why women are more commonly infected than men. Bacteria need only ascend a shorter distance up the urethra to their bladder (Figure 1). Bacteria readily migrate into the vagina and beyond. Therefore, intercourse is contributory to spreading pathogens throughout the area.

Urine from females has also been shown to provide a better medium for bacterial growth, because it is slightly more alkaline than that of males. This is especially true during pregnancy. Once the pH of urine becomes more alkaline, bacterial growth is enhanced.

Predisposing Factors

Calculi. Most kidney stones are caused by excessive production and deposition of calcium salts. Stones may also form from carbonate, oxalate, urate or other crystalloids. Alkalinization of urine decreases the solubility of calcium and increases the possibility of formation of renal calculi.

Obstruction. Obstruction to urine flow fosters infection. Once an infection begins in the presence of an obstruction or lesion, treatment is extremely difficult.

Anatomical abnormalities are frequently the cause of UTIs in infants and children. When infection occurs in this age group, suitable diagnostic studies should be performed. At this age, the incidence of abnormality is approximately the same for both sexes. Disorders most often encountered include stenosis (narrowing) of the external urethral meatus (opening) especially in males, and abnormalities in the collecting system.

Tumors located in the genitourinary system may produce partial or complete obstruction of urine flow. In males over 60 years of age, benign prostatic

hypertrophy and carcinoma of the prostate often produce obstruction to urine flow at the level of the bladder neck. Benign prostatic hypertrophy is the most common abnormality which predisposes males to UTI.

Pregnancy. It is reported that 5 to 7 percent of pregnant women have asymptomatic bacteriuria (bacteria in the urine). Left untreated, 20 to 40 percent develop acute symptomatic UTIs some time prior to delivery. This may be due to urethral dilation which occurs during pregnancy. The dilated urethra allows easier entrance of bacteria.

Mechanical Factors. The most common mechanical factor that leads to development of UTI is catheterization or instrumentation of the bladder. As stated above, the majority of hospital-acquired urinary tract infections occur in patients who have been catheterized at some time during their hospital stay.

Neurologic Disorders. A neurologic dysfunction that would fail to initiate or control bladder emptying predisposes the patient to UTI. This is seen in persons with spinal cord tumors, spinal cord transection, or diabetic neuropathy.

Categorizing Urinary Tract Infections

Urinary tract infections are differentiated by pathogenic location into lower and upper tract infections. Infections of the lower tract are referred to as **cystitis** (bladder) and **urethritis** (urethra). Upper tract infections involve one or both kidneys causing **pyelonephritis**.

In a small number of patients, bacteria within the bladder may enter the upper urinary tract to invade the mucosa of the kidney. One or both kidneys may be infected to cause acute pyelonephritis. Patients with pyelonephritis are extremely ill, with fever of 104 to 105° F, shaking chills, paralytic ileus, and excruciating pain in the abdomen and back. When pyelonephritis follows an interference of normal urine flow (renal stones, tumor or enlarged prostate), or when urine flow is decreased, it must be re-instituted quickly. If not, total and irreversible damage to the affected kidney may result.

Another problem with pyelonephritis is that once therapy is initiated,

leukocytes and bacteria begin to disappear from urine. The previously turbid urine of infected individuals suddenly appears clear, suggesting that it is bacteria-free. Because of this dramatic clearing of urine, the patient may falsely believe infection is over and stop taking the medication.

The resistant Gram-negative aerobic microorganisms found in chronic UTIs occasionally spread to the blood to cause septicemia. This may lead to circulatory collapse and shock, which can be fatal unless recognized and properly treated.

There are other means to categorize UTIs. **Chronic infections** are of lower grade but they linger over a prolonged period of time. **Symptomatic** refers to the fact that the patient experiences bothersome effects such as burning on urination, back pain, fever, etc. With **asymptomatic** infections, the pathogens are still present at infective level, but the patient is not seriously aggravated by signs of disease. Nonetheless, asymptomatic infections should be treated.

With **complicated infections**, there is associated structural, functional, or neurological abnormality such as enlarged prostate or kidney stones. **Recurrent infections** are subdivided into **relapse**, in which the recurring infection is caused by the same strain of microorganism; and **reinfection**, which involves a different or mutated causative organism.

Acute (Uncomplicated) Infections. The vast majority (80 to 90 percent) of community acquired infections are caused by the uropathogen *Escherichia coli*. The Gram-positive bacteria *Enterococcus* species and *Staphylococcus saprophyticus* account for 10 percent of community-acquired UTIs.

For hospitalized patients (especially those who have been catheterized or have undergone cystoscopic examination), *Proteus* species, *Klebsiella* species, *Enterobacter* species and *Pseudomonas aeruginosa* are often involved.

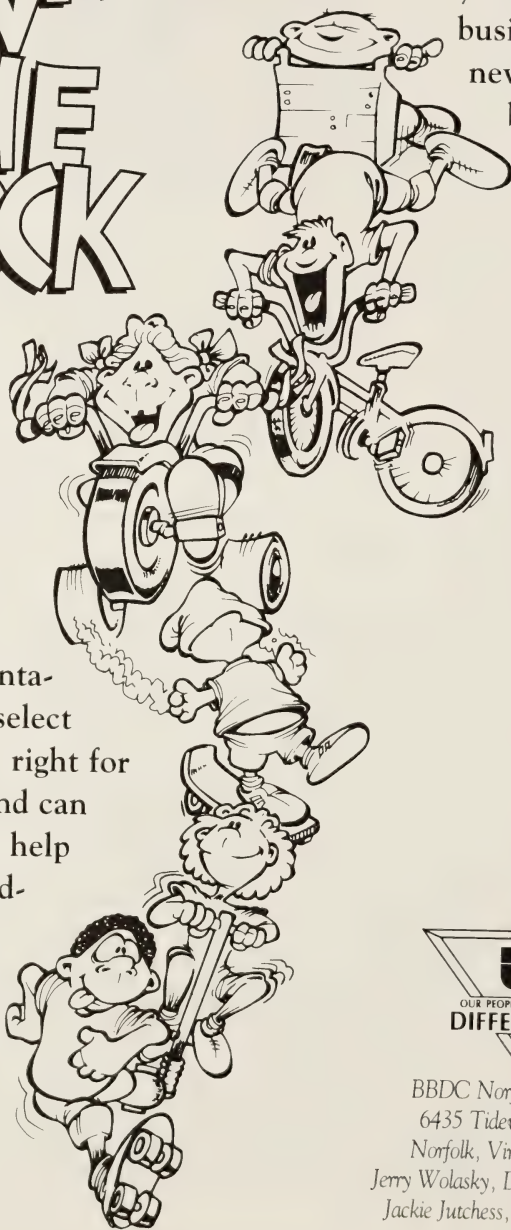
Chronic (Complicated) Urinary Tract Infections. Patients usually present with symptoms of acute uncomplicated infection, but have a long history of repeated infections. Instrumentation or catheterization, pregnancy, and kidney stones all increase the possibility of a complicated UTI.

Unlike acute infections, chronic UTIs

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are usually characterized by more than one species of microorganism. Common ones include *Proteus*, *Klebsiella*, *Enterobacter*, *Enterococcus*, *Pseudomonas*, *Staphylococcus*, and possibly, *Candida*. *E. coli* are responsible for about 50 percent of chronic complicated infections.

Confirming the Diagnosis

General symptoms often indicate that the patient has a UTI. However, it is recommended that the physician confirm the probable diagnosis with a urinalysis. A normal urine sample contains a minimum bacteria count of 1000/mL. These are present because they are picked up as urine is excreted from the body. Urine is sterile when it leaves the kidneys, bladder and urethra. Bacterial counts of 100,000/mL of urine may be seen in 95 percent of all cases of pyelonephritis. This concentration is accepted by many authorities as the point where significant bacteriuria exists, and active treatment with appropriate anti-microbial therapy should be undertaken.

It is difficult to collect a reliable urine specimen in females because bacteria in the vaginal vestibule can easily contaminate the sample. The most common and reliable method is referred to as the **clean midstream-catch** technique. The woman cleanses the area around the opening of her urethra. The labia are held apart so that urine can escape the urethra directly, without touching any external surface. After urination begins, as close to the midpoint as possible, she collects a "midstream" sample as she continues to urinate. This technique minimizes the chance of capturing uninvolved bacteria in the sample.

When bacteria are found in the sample and the count suggests infection, the physician will usually prescribe medical treatment before the organism is identified, because most UTIs are caused by *E. coli* or related coliform bacteria. Cultures should still be made and positive identification confirmed, however. If the initial treatment has been effective, the bacterial count should drop within 24 to 48 hours. A 10-day course of therapy is normally adequate for most acute uncomplicated infections. If results of culturing show an unexpected bacterial species, or one that is unresponsive to the drug, therapy should be changed to the ap-

propriate agent.

Occasionally, UTIs may exist without evidence of bacteriuria. This is especially true when infection occurs high in the kidneys or with obstruction distal to the infection. An absence of significant bacterial count, in the presence of definite symptoms of UTI, should not prevent initiating appropriate drug therapy.

Home Test For Bacteriuria. Home tests for UTI (e.g., Microstix-3, Biotel/UTI) depend on bacterial conversion of nitrate (derived from dietary metabolites) to nitrite. The test strips have an acidic pH at which nitrite reacts with p-arsanilic acid to form a diazonium compound. This, in turn, couples with N-(1-naphthyl) ethylenediamine which is impregnated in the strip to initiate a pink color. If the test is positive, as indicated by a pink color, the user should suspect that bacteria are present in the urine. Test results are qualitative, not quantitative.

When recommending these OTC products, the person should be instructed to remove the reagent strips from the foil just prior to testing urine. The reagent area must not be touched. The strip is dipped into a sample of urine which is obtained in the early morning, to assure adequate time for incubation overnight, and the results read at the time specified on the package. The test is performed on three

consecutive mornings.

The urine specimen should be collected in a clean, dry container and tested as soon as possible after collection. If testing cannot be performed within an hour of voiding, the specimen should be refrigerated immediately and tested within eight hours. In this case, the specimen should be returned to room temperature before testing.

Therapy for Urinary Tract Infections

Most urinary tract infections readily respond to drug therapy. Too often, however, they persist in latent form, or become chronic. Nearly all, other than those that were untreated or result from poor patient compliance with therapy, are caused by re-introduction of the organisms from an external source.

In the overwhelming majority of uncomplicated UTIs, a major reason for poor compliance is that symptoms disappear in a few days with or without drug treatment. Patients must be convinced to continue therapy for the full course of treatment even if they feel better.

Acute Uncomplicated Infections. Treatment of acute uncomplicated UTI is fairly well defined (Table 1). The quinolone derivatives (e.g. ciprofloxacin/Cipro, and norfloxacin/Noroxin) have

Table 1

Representative Commercially Available Drugs Specifically Indicated for Treating Chronic Urinary Tract Infections

Generic Name	Trade Name	Dosage Forms
Cinoxacin	Cinobac	Capsules 250 & 500 mg
Ciprofloxacin	Cipro	Tablets 250, 500 & 750 mg
Methenamine hippurate	Hiprex Urex	Tablet 1 gm
Methenamine mandelate	Mandelamine	Tablet 500 mg & 1 gm Suspension 250 mg/5 mL, 500 mg/5 mL Granules 1 gm
	Mandemeth	Tablets ECT 500 mg & 1 gm
Nalidixic acid	NegGram	Tablets 250 & 500 mg, 1 gm Suspension 250 mg/5 mL
Nitrofurantoin	Furadantin Furalan Furan Furanite	Tablets 50 & 100 mg Suspension 25 mg/5 mL
Nitrofurantoin (macrocrystals)	Macrochantin	Capsules 25, 50 & 100 mg
Norfloxacin	Noroxin	Tablets 400 mg
Ofloxacin	Floxin	Tablets 200, 300 & 400 mg

become widely used for acute UTIs.

Chronic Uncomplicated Infections. The most difficult UTIs to treat are those where urine flow is obstructed. Unless corrective surgery or appropriate urologic procedures are performed to correct the situation, infections will probably continue to recur in spite of repeated drug therapy.

Another chronic condition is referred to as infection of "stagnant urine." For these patients, nitrofurantoin or a methenamine salt may be effective in keeping the condition asymptomatic.

In non-responsive infections, a quinolone may be tried. Likewise, sulfonamides, penicillins, cephalosporins, tetracyclines, erythromycin, chloramphenicol or aminoglycoside antibiotics are used.

Drugs Specifically Indicated for Treating Urinary Tract Infections

Nitrofurantoin. The one indication for nitrofurantoin (e.g., Furadantin) and nitrofurantoin macrocrystals (e.g., Macrocrystin) is management of UTIs, because therapeutically active levels are achieved in urine. These drugs are useful for both prevention and suppression of chronic infections, because of the low frequency of development of bacterial resistance.

Their spectrum of activity includes *E. coli*, Enterococci and Staphylococci. Enterobacter, Proteus and Klebsiella are less susceptible while Pseudomonas is ordinarily resistant. Antibacterial action is thought to be due to interference with several important bacterial enzyme systems, thereby inhibiting their replication and suppressing growth. Bacterial resistance to nitrofurantoin develops slowly and rarely.

The most common adverse reactions include gastrointestinal distress, such as anorexia, nausea, vomiting and occasional diarrhea and abdominal cramping. These can best be minimized by reducing dosage. Nitrofurantoin should be taken with food. One of its metabolites can impart a brownish coloration to urine. This is of no consequence and patients should be advised not to be alarmed if it occurs.

Some authorities suggest that if therapy is continued beyond 10 days, dosages should be reduced to one-half. Then after another 10 days, the dose should be decreased in half again, i.e.,

to one-fourth of the original dose.

Methenamine Salts. (Hiprex, Urex, Mandelamine) Methenamine has been preferred for long-term suppression of recurrent chronic UTI when the contributing complications are kidney stones or an inflamed prostate. Reasons for this preference include relatively low toxicity and rare bacterial resistance since it is antiseptic rather than antibiotic. Methenamine is not useful in management of acute UTIs.

In acid urine, methenamine is hydrolyzed to ammonia and formaldehyde, the active antibacterial agent. It is therefore imperative that urine acidity be maintained below pH 5.5. For patients whose urine is not naturally maintained at pH 5.5 or below, it may be acidified with ammonium chloride, or large doses of ascorbic acid. Patient response to the latter is variable.

High doses of urinary alkalinizers, such as sodium bicarbonate may inhibit conversion of methenamine to formaldehyde, and should be avoided. Nitrazine paper can be used to test urine pH.

It is not uncommon for patients to be on methenamine therapy for several years. Methenamine finds greatest use in treatment of UTIs that do not respond to more effective (and toxic) anti-infectives. This is especially true when there is a complicating factor such as an indwelling catheter, or a structural or functional abnormality which is the focus of the chronic condition.

Adverse effects are rare, the most common being gastrointestinal irritation (nausea, vomiting and diarrhea). Occasionally the liberated formaldehyde (or acidified urine) will produce further urinary tract irritation or discomfort. Formaldehyde imparts odor to the urine, so the patient should be informed. It is unwise to inform the patient that the smell is caused by formaldehyde, for obvious reasons.

Quinolone Derivatives. Five quinolone derivatives are currently available, with more on the way. The earliest quinolones, nalidixic acid (NegGram) and cinoxacin (Cinobac), were outstanding antimicrobials in their day. Over the years, once-susceptible organisms have developed resistance to them.

During clinical trials, it was shown that ciprofloxacin (Cipro) and norfloxacin (Noroxin) had significantly wider spectra of activity, lower oc-

currence of resistance and fewer side effects than their predecessor quinolones. Shortly after release on the market, both Cipro and Noroxin were in the top-100 prescribed drugs. Currently, they are in the top-50 list.

The newest quinolone derivative, ofloxacin (Floxin), also has a broad spectrum. It is officially indicated for UTIs and other infections.

Briefly, their mechanism of action is thought to be due to an ability to enter susceptible bacteria and bind with bacterial DNA-gyrase. This enzyme converts relaxed (i.e., inactive) bacterial DNA into its active form. Quinolones terminate this conversion, promote breakage of bacterial DNA strands, and therefore, are bactericidal.

Drug interactions have been reported. Aluminum and calcium-containing antacids hinder absorption of both agents, and should not be taken within an hour of each other. Ciprofloxacin appears to inhibit the metabolism of theophylline to increase its toxicity. Patients receiving both drugs should be monitored for signs of theophylline toxicity (e.g., nausea, vomiting, tremors, restlessness, palpitations and seizures).

The optimal time to take either ciprofloxacin or norfloxacin is on an empty stomach, with lots of fluid. Food can delay absorption of both drugs. The manufacturer of ciprofloxacin states that the dose can be taken with meals if needed. With norfloxacin, its manufacturer adds that food may decrease absorption and, therefore, recommends taking it on an empty stomach.

Ciprofloxacin has been reported to cause photosensitivity reactions. Patients taking it should avoid prolonged or excessive exposure to sunlight or ultraviolet "tanning" light.

Advising Patients on Urinary Tract Infections

Patients with UTIs should be reminded to comply with their physician's instructions involving therapy. They should drink at least 8 to 10 glassfuls of liquid each day.

A physician may prescribe a urinary analgesic such as phenazopyridine (Pyridium) for short-term (up to two days) management of pain and other discomfort of UTI. Patients should understand that the medication will impart a reddish-orange color to urine and may stain clothing.

Dickinson's Pharmacy

Jim Dickinson

What if there were no pharmacies? This isn't exactly a hypothetical question. Small, one-horse towns have been losing their only drugstore for many years, and now densely populated urban areas have been losing theirs, as well.

The reasons are varied. Population shifts can make marginally viable businesses not viable. Crime can force stores to close. Death or illness can shut down a pharmacy forever when another pharmacist willing to be an owner can't be found.

I'm not thinking of these factors when I pose the question, *What if there were no pharmacies?*

I am thinking about "managed care" (more accurately, "managed cost") policies that by their level or reimbursement and administrative complexity logically -- but unwittingly -- invite the pharmacy owner to go into some other line of work.

Some might think that such policies concern only those most directly involved -- the payor and the payee. But pharmacists know that such policies would most powerfully impact the patient if they forced pharmacies to close.

So why shouldn't the patients be asked to consider the consequences of such policies? Our whole social system, from marketplace through government, is based on the law of supply and demand.

To the extent that "managed care" policymakers see pharmacies as being in inexhaustible supply, existing to be picked as the pioneers once picked off buffalo and redwood trees without any thought for tomorrow,

then patients, employers and politicians can hardly be blamed for assuming the same attitude.

Isn't it up to pharmacy to say, "Hey, we're hurting -- and that could hurt you"?

Shouldn't those with the most at stake -- patients who depend on being able to go physically to a pharmacy whenever the need arises -- be asked to consider where they would be if there were no pharmacy to go to?

In other scenarios that are not so life-and-death, citizens have become sufficiently aroused to alter policies that were adverse to their interests.

Shouldn't those with the most at stake be asked to consider where they would be if there were no pharmacy to go to?

Consider various threats to close a local school because of dwindling enrollments, close the bus depot, or the post office, or the newspaper recycling service, or a local park, or

Sometimes an apathetic citizenry will just shrug its collective shoulders and grumble a lot.

But very often, it only takes an incendiary to organize them into an effective fight.

And so it might be in the case of pharmacy's collective fight to get a better deal from managed care.

The message below is intended to

be copied, enlarged into a poster, and displayed in a pharmacy. It can also be made into a local direct mail flyer, a pharmacy bagstuffer, or a newspaper advertisement. Start winning the war of public opinion now!

What if There Were No Pharmacies?

And all medicines came by mail?

Don't take it for granted that there will always be retail pharmacies to go to when you need a prescription filled unexpectedly.

Insurance plans, Medicaid and other third parties are now shifting prescription coverage away from local pharmacies in the mistaken idea that this saves them money.

Where would you go in an emergency? The nearest hospital, where there are long waits and disinterested service?

Who would you call for advice when you're doubtful about a drug effect? Your busy doctor, who is hardly a "second opinion" on drug effects and interactions?

Who would check your prescription against your other medications (prescribed perhaps by other doctors) in case of a conflict? Somebody at an 800 number?

Who would your doctor call when he wants you to modify your prescribed therapy based on your reactions to it? The same "somebody" -- or somebody else? And what do they know?

Continued on Page 10...

Dickinson's Pharmacy

Continued from Page 9.

What if you forget to take your medicine with you on a trip? There would be no pharmacies anywhere!

Suppose the mailman brought the wrong medicine? It happens more than you think!

Don't take your local pharmacy for granted. Your local pharmacy is hands-on professional care, right where you can see it and get immediate assistance at any time.

Support this continued service to the neighborhood by opposing any more to send your prescriptions out of town to a mail-order prescription processor.

For your continuing health and safety, local pharmacies are too valuable to lose!

This feature is presented on a grant from "Dickinson's Pharmacy -- The Independent Voice," a professionally stimulating monthly newsletter available for \$45 a year plus your retail pharmacy's label from Ferdic, Inc., PO Box 848, Morgantown, WV 26507-0848.

PHARM PAC



A POLITICAL ACTION COMMITTEE REPRESENTING MARYLAND'S PHARMACISTS

The *Baltimore Business Journal* reported that from November 1986 through November 1989, **Pharm PAC** made political action contributions of \$10,905. An average of \$3,635 per year.

In 1990, **Pharm PAC** has made \$20,845 in contributions to 115 different candidates. This represents an almost four-fold increase in our activity!

In August, pharmacists around the state were asked to contribute to **Pharm PAC**. This political action committee was created to help keep the interests of pharmacy in the minds of state legislators through campaign fund contributions. Our goal is to raise at least \$25,000 in the next two years. **BUT**, it can't be done without your personal commitment.

Pharm PAC Contributors

August 1 through October 31, 1991

Fallston Pharmacy		\$500
Powell Pharmacy	Charles Powell	\$500
Edwards & Anthony	Bill Popomaronis	\$100
Tuxedo Pharmacy	Arnold Davidov	\$500
Medicine Shoppe	Tom Weiland	\$ 50
Arcade Pharmacy	Lance Berkowitz	\$500
Northern Pharmacy	Martin Mintz	\$500
Elwin Alpern		\$500
Hudson's Pharmacy	Donald Young	\$500
James Drugs	Avi Pelta	\$500
R.J. Zaycer		\$ 50
Walsh McCagh Pharmacy		\$500
Lykos Pharmacy	Nick Lykos	\$500
Jarrettsville Pharmacy	Arnold Neuberger	\$500
Village Drugs	David Braunstein	\$100

*If your name is on this list, many thanks for your support of **PHARM PAC**. If it's not, don't you think now is the time you got involved in protecting pharmacy's future?*

Support Maryland's only political action committee for pharmacists!

Authority: Arnold Davidov, Treasurer

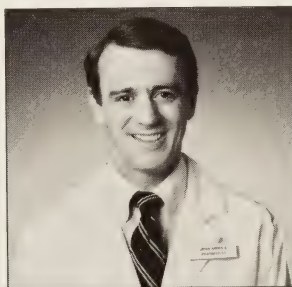
Important figures in diabetes care



Diabetes is the **No. 7** cause
of death in the US¹



Diabetes is the **No. 1** cause of new
blindness in persons aged 20-74¹



Pharmacists see patients with diabetes
5 times more often than do physicians.
These customers spend 3 to 8 times more
annually in the pharmacy than persons
without diabetes.²



Global Excellence in Diabetes Care

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can offer you and your customers with diabetes.

1. *Diabetes Surveillance, 1980-1987*. Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes*. Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

Urinary Incontinence In Adults

National Institutes of Health
Consensus Development Conference Statement

Urinary incontinence, the involuntary loss of urine so severe as to have social and/or hygienic consequences, is a major clinical problem and a significant cause of disability and dependency. Urinary incontinence affects all age groups and is particularly common in the elderly. At least 10 million adult Americans suffer from urinary incontinence, including approximately 15 to 30 percent of community-dwelling older people and at least one-half of all nursing home residents. The monetary costs of managing urinary incontinence are conservatively estimated at \$10.3 billion annually, and the psychosocial burden of urinary incontinence is great.

Urinary incontinence is a symptom rather than a disease. It appears in a limited number of clinical patterns, each having several possible causes. In some cases, the disorder is transient, secondary to an easily reversed cause such as a medication or an acute illness like urinary tract infection. Many cases are chronic, however, lasting indefinitely unless properly diagnosed and treated.

There is a persistent myth that urinary incontinence is a normal consequence of aging. While normal aging is not a cause of urinary incontinence, age-related changes in lower urinary tract function predispose the older person to urinary incontinence in the face of additional anatomic or physiologic insults to the lower urinary tract or by systemic disturbances such as illnesses common in older people.

Even frail nursing home residents or persons being cared for by family caregivers often have urinary incontinence that can be significantly improved or cured. Persons with urinary incontinence should be alerted to the importance of reporting their symptoms to a health care professional and of asserting their right to proper assessment, diagnosis, and treatment. The first steps to treatment are acknowledgment of the problem and appropriate assessment and diagnosis.

nificant clinical problem by health providers; lack of education of health providers regarding new research findings; inadequate staffing in the long-term care setting; and the persistent major gaps in our understanding of the natural history, pathophysiology, and most effective treatments of the common forms of urinary incontinence. The amount of basic research as well as research focusing on prevention is meager.

To resolve issues regarding the incidence, causes, and consequences

*At least 10 million adult Americans
suffer from urinary incontinence.*

Knowledge of the occurrence, causes, consequences, and treatment of the specific forms of urinary incontinence has increased. While new diagnostic tests have been developed, well-defined guidelines are needed for their application. Similarly, despite numerous new potential therapies, opinions differ widely concerning the best approach to many specific forms of the disorder. The most common treatments include pelvic muscle exercises and other behavioral treatments, local and systemic drug therapies, and a variety of surgical approaches.

The number of patients with urinary incontinence who are not successfully treated remains surprisingly high. This is due to several factors, including underreporting by patients; underrecognition as a sig-

of urinary incontinence in adults, the National Institute on Aging and the Office of Medical Applications of Research of the National Institutes of Health, in conjunction with the National Institute of Diabetes and Digestive and Kidney Diseases, the National Center for Nursing Research, the National Institute of Neurological and Communicative Disorders and Stroke, and the Veterans Administration, convened a Consensus Development Conference on Urinary Incontinence in Adults on October 3-5, 1988. After a day and a half of presentations by experts in the relevant fields involved with urinary incontinence, a consensus panel consisting of representatives from geriatrics, urology, gynecology, psychology, nursing, epidemiology, basic sciences, and

the public considered the evidence and developed answers to the following central questions:

- What is the prevalence and clinical, psychological, and social impact of urinary incontinence among persons living at home and in institutions?
- What are the pathophysiological and functional factors leading to urinary incontinence?
- What diagnostic information should be obtained in assessment of the incontinent patient? What criteria should be employed to determine which tests are indicated for a particular patient?
- What are the efficacies and limitations of behavioral, pharmacological, surgical, and other treatments for urinary incontinence? What sequences and/or combination of these interventions are appropriate? What management techniques are appropriate when treatment is not effective or indicated?
- What strategies are effective in improving public and professional knowledge about urinary incontinence?
- What are the needs for future research related to urinary incontinence?

are twice as high in women as in men, and are higher in older than in younger adults. Though these community rates are alarmingly high, rates in nursing homes are even higher. Half or more of the 1.5 million Americans in nursing homes suffer from urinary incontinence.

Little is known about the natural history of urinary incontinence, including age at onset, incidence rates, progression, and spontaneous remission. Limited data exist on associated morbidity and functional impairment. To date, most studies have been conducted in whites, and data are needed on the occurrence in nonwhite ethnic groups.

Though urinary incontinence is a symptom of many conditions, defining risk factors would be extremely useful for identifying high-risk persons and remediable environmental causes. While age, gender, and parity are established risk factors, many other factors have been suggested but not rigorously proven. These include urinary infection, menopause, genitourinary surgery, lack of postpartum exercise, chronic illnesses, and various medications. Risk factor identification is essential for a concerted effort at prevention.

use of absorbent materials without having their difficulty properly diagnosed and treated.

The psychosocial impact of incontinence in the community falls on individuals and their care providers. Studies of women show that the condition is associated with depressive symptoms and leads to embarrassment about appearance and odor, although such reactions may be related more to illness than to incontinence. Excursions outside the home, social interactions with friends and family, and sexual activity may be restricted or avoided entirely in the presence of incontinence. Spouses and other intimates also may share the burden of this condition. A highly conservative estimate of the direct costs of caring for persons with incontinence of all ages in the community is \$7 billion annually in the United States.

In Nursing Homes

Many physicians fail to recognize the clinical impact of urinary incontinence in nursing homes, and very few nursing home residents with incontinence have had any type of diagnostic evaluation. In this setting, fecal incontinence, physical and mental impairment, pressure sores, and urinary tract infections are commonly associated with urinary incontinence, but cause-and-effect relationships are not clear. Many nursing home residents who are incontinent are managed with indwelling catheters, which carry an increased risk of significant urinary tract infection, and the use of such devices varies widely. The odor of urine that permeates many nursing homes can be repellent to residents, staff, and potential visitors. Managing those with incontinence presents a major problem to insufficient and often untrained staff. The annual direct cost of caring for incontinence among nursing home patients is approximately \$3.3 billion.

There is a persistent myth that incontinence is a normal part of aging

1. What is the prevalence and clinical, psychological, and social impact of urinary incontinence among persons living at home and in institutions?

A. Occurrence and Risk

Estimates of the occurrence of urinary incontinence depend on the nature of the study population and definition of the disorder. Prevalence rates range from 8 to 51 percent; an estimate of 15 to 30 percent for community-dwelling older persons seems reasonable, and of these, 20 to 25 percent may be classified as severe. Prevalence rates

B. Clinical, Psychological, and Social Impact

In the Community

Because only about half of the people with incontinence in the community have consulted a doctor about the problem, the true extent and clinical impact of urinary incontinence is not known. Rashes, pressure sores, skin and urinary tract infections, and restriction of activity are some of the problems that could be prevented or treated if the underlying incontinence were brought to medical attention. Many people with incontinence turn prematurely to the

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2. What are the pathophysiological and functional factors leading to urinary incontinence?

Continence requires a compliant bladder and active sphincteric mechanisms, such that maximum urethral pressure always exceeds intravesical pressure. Normal voiding requires sustained and coordinated relaxation of the sphincters and contraction of the urinary bladder.

These functions are regulated by the central nervous system through autonomic and somatic nerves. The system requires the integration of visceral and somatic muscle function and involves control by voluntary mechanisms originating in the cerebral cortex. These voluntary mechanisms are learned and culturally prescribed (i.e., toilet training).

Incontinence can be produced by any pathologic, anatomic, or physiologic factor that causes intravesical pressure to exceed maximum urethral pressure. Intravesical pressure can be raised by involuntary detrusor contractions (unstable bladder or detrusor hyperreflexia), by acute or chronic bladder overdistension (urinary retention with overflow), or by an increase in intra-abdominal pressure. Similarly, a decrease in urethral pressure may occur as a result of uninhibited sphincter relaxation (unstable urethra), loss of pelvic floor support (genuine stress incontinence), and urethral wall defects from trauma, surgery, or neurologic disease.

the bladder outlet leads to leakage of urine as intra-abdominal pressure is raised above urethral resistance while coughing, bending, or lifting heavy objects. Volume of urine leakage is generally modest at each occurrence and, in uncomplicated cases, postvoid residual volume is low. Stress incontinence has many causes, including direct anatomic damage to the urethral sphincter (sphincteric incontinence), which may lead to severe, continuous leakage, and weakening of bladder neck supports, as is often associated with parity.

Urge incontinence occurs when patients sense the urge to void (urgency) but are unable to inhibit leakage long enough to reach the toilet. In most, but not all, cases, uninhibited bladder contractions contribute to the incontinence. Urine loss is moderate in volume, occurs at several hour intervals, and postvoid residual volume is low at several hour intervals. Among the causes of urge incontinence are central nervous system lesions such as stroke or demyelinating disease, which impair inhibition of bladder contraction, and local irritating factors such as urinary infection or bladder tumors. In many cases of urge incontinence, no specific etiology can be identified despite detailed clinical and laboratory evaluation.

An important variant of urge incontinence is reflex incontinence, in which urine is lost due to uninhibited

when the bladder cannot empty normally and becomes overdistended, leading to frequent, sometimes nearly constant, urine loss. Causes include neurologic abnormalities

When incontinence is due to stress and urge, pharmacologic and behavioral treatment may be employed with surgery.

that impair detrusor contractile capacity, including spinal cord lesions, and any factor that obstructs outflow, including medications, tumors, benign strictures, and prostatic hypertrophy.

Many cases of urinary incontinence fall into the mixed category, displaying some aspects of more than one of the major subtypes, both clinically and on extensive laboratory evaluation.

The term "functional" incontinence is applied to those cases in which the function of the lower urinary tract is intact, but other factors such as immobility or severe cognitive impairment result in urinary incontinence.

It should be clear that urinary incontinence can be caused by multiple and often interacting conditions. Of particular importance are the transient or reversible factors such as infection, delirium, and drugs. These causes, which may be common in the elderly patient, should be carefully considered in the pathophysiology of urinary incontinence.

There are age-related changes in the lower urinary tract that increase its vulnerability to both chronic and transient factors. Increases in uninhibited contractions, nocturnal fluid excretion, and prostate size, accompanied by decreases in bladder capacity and flow rate, all lead to greater susceptibility to urinary incontinence in the face of stresses associated with disease, functional impairment, or environmental factors.

More than half of the 1.5 million Americans in nursing homes suffer from urinary incontinence.

Subtypes of Urinary Incontinence

The most commonly encountered clinical forms of urinary incontinence in adults are stress incontinence, urge incontinence, overflow incontinence, and a mixed form. In stress incontinence, dysfunction of

initiated bladder contractions in the absence of the symptoms of urgency. In addition, many persons suffer from very frequent symptoms of urgency and are only able to remain continent by conducting their activities in the proximity of restrooms.

Overflow incontinence occurs

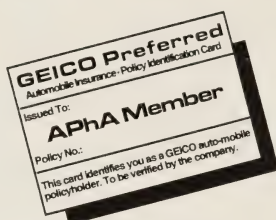
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In older persons, cognitive decline, musculoskeletal impairments, and restricted access to toilets may all convert the marginally continent system to incontinence.

3. What diagnostic information should be obtained in assessment of the incontinent patient? What criteria should be employed to determine which tests are indicated for a particular patient?

Evaluation and therapy must be tailored to the individual, taking into account clinical, cognitive, functional, and residential status in addition to the potential for correcting the problem. Just as a child is not simply a young adult, octogenarians differ from persons in their forties. Patients with stress urinary incontinence are quite dissimilar from those with uninhibited contractions and unstable bladders. Proper diagnosis and active case finding are imperative.

Core Evaluation

History

The evaluation of all patients with incontinence requires a thorough history, including medical, urologic, gynecologic, and neurologic assessment, with particular attention to those factors that influence bladder function. The duration, frequency, volume, and type of incontinence should be described and validated by a voiding diary. Other important information includes associated illnesses, previous operations, and current medications.

Physical Examination

Physical examination is required, with emphasis on mental status; mobility and dexterity; and neurologic, abdominal, rectal, and pelvic findings. A provoked full-bladder stress test is recommended. Since prostate enlargement is often asymmetric, the size of the prostate as es-

timated on rectal exam may be misleading when evaluating the possible contribution of prostatic hypertrophy to urinary obstruction.

In addition to the history and physical examination, core measurements to be obtained in all patients are urinalysis, serum creatinine or blood urea nitrogen, and postvoid residual urine volume. Other tests such as urine culture, blood glucose, and urinary cytology may be useful.

Based on the findings from the core evaluation, a decision for treatment or more definitive evaluation is made, taking into consideration the type and degree of incontinence.

Specialized Studies

The tests currently available for specialized study include:

- Cystometrogram—to be used as the basic study in cases requiring more than core evaluation, should be accompanied by measurement

or estimation of abdominal pressure.

- Electrophysiologic sphincter testing (EMG).
- Ultrasound of the bladder or kidneys may detect residual urine or hydronephrosis.
- Cystourethroscopy with or without cytology is indicated in patients with hematuria or the recent onset of urgency or urge incontinence who are at increased risk for carcinoma.
- Uroflowmetry has wide application in the evaluation of obstructive disease in men but a limited role in the evaluation of women.
- Videourodynamic evaluation requires special expertise. Its role is limited to the more elusive incontinence problems.
- Urethral pressure profilometry is a controversial test. Its predictive value has been questioned, and it requires further validation before it can be recommended for widespread use.

These numerous noninvasive and invasive tests must be used selectively. Examples of patients rarely requiring further diagnostic testing after the core examination include the young woman with classic stress incontinence or the 80-year-old woman with a recent stroke and the new onset of urge incontinence. Patients with stress incontinence and a significant urge component or those in whom previous operations have failed may require combined cystography and fluoroscopy with a complete urodynamic evaluation. Some patients with urge or mixed incontinence, or those who are not helped by empiric therapy or operation, also will require more complete urodynamic testing. Some patients may not be candidates for sophisticated studies due to inability to cooperate or a poor prognosis for correction. Armed with this information, the investigating physician should be able to reach an accurate diagnosis leading to appropriate therapy.

4. What are the efficacies and limitations of behavioral, pharmacological, surgical, and other treatments for urinary incontinence? What sequences and/or combination of these interventions are appropriate? What management techniques are appropriate when treatment is not effective or indicated?

A. General Principles of Treatment

- All persons with incontinence should be considered for evaluation and treatment.
- Treatment decisions should be based on a diagnosis made after a reasonable evaluation of anatomy and function of urine storage and emptying.
- Treatment for incontinence is given to a specific individual, whose personality, environment, expectations, and clinical status are important determinants of treatment modalities to be used and the order of their application.
- The patient requires sufficient information and explanation to be able to make a choice among therapeutic options.
- Environmental constraints in the community or in an institution that may impede treatment are common, and strategies to circumvent impediments are a part of the therapy.
- In particular, availability of adequate numbers of properly constructed public toilets is an important adjunct to incontinence management.

B. Pharmacologic Treatment

Most drugs currently used in managing the varied causes of urinary incontinence have not been studied in well-designed clinical trials. Nevertheless, it has been suggested that many agents are beneficial, especially for urge incontinence due to uninhibited detrusor contractions. For these patients, drugs that increase bladder capacity can be helpful. One attendant risk is the precipitation of retention. Ac-

cordingly, outlet obstruction or a weak detrusor should be looked for as possible contraindications to these agents.

Bladder Relaxants

These agents are generally used for urge incontinence:

Anticholinergics

Anticholinergic agents inhibit detrusor contraction and may produce increased bladder capacity and delay and reduction in amplitude of involuntary contractions. Propantheline is frequently effective, although high doses may produce unacceptable side effects such as dry mouth, dry eyes, constipation, confusion, or precipitation of glaucoma.

Direct Smooth Muscle Relaxants

These antispasmodics work directly on bladder muscle, but they have a mild anticholinergic effect as well. A randomized, double-blind, placebo-controlled study has shown benefit with oxybutynin in patients with detrusor instability, some but not all of whom were incontinent. Favorable reports also exist about flavoxate and dicyclomine, the other two agents in this class.

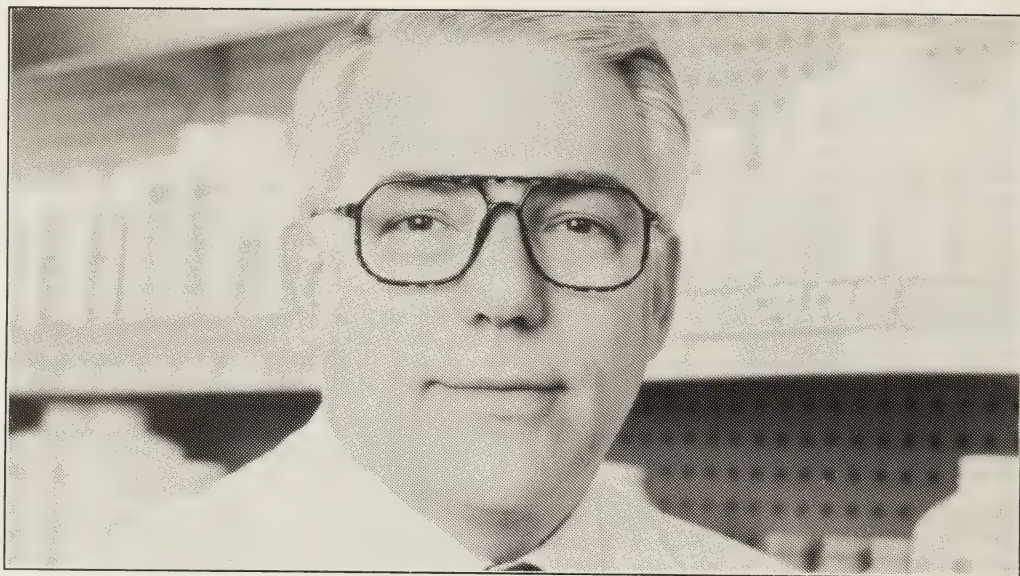
Calcium Channel Blockers

These agents, used clinically for cardiovascular indications, have a depressant effect on the bladder as well, but they have not been studied rigorously for the treatment of urge incontinence in comparison with other agents. In the patient being considered for treatment for heart disease, the bladder effects of calcium antagonists must be kept in mind for both their potential benefit as well as risk of retention.

Imipramine

This tricyclic antidepressant has anticholinergic and direct relaxant effects on the detrusor and an alpha adrenergic enhancing (contracting)

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effect on the bladder outlet, all of which enhance continence. Although imipramine is commonly used, potential side effects of postural hypotension and sedation as well as all peripheral anticholinergic effects make caution imperative when considering this agent in older persons.

Bladder Outlet Stimulants

Alpha adrenergic agonists, used in treatment of stress incontinence, produce smooth muscle contraction at the bladder outlet and may improve continence. Pseudoephedrine and ephedrine both are active, but phenylpropanolamine has been used most often, and objective benefit by urodynamic study has been shown.

Estrogens

Because urinary incontinence increases in women with increasing age, and because menopause results in estrogen deficiency, estrogen replacement has been thought to be helpful for urinary incontinence. Several studies have shown no improvement in stress incontinence, but women with postmenopausal urge incontinence, urgency, and frequency have shown improvement. Long-term use should be considered in view of other risks and benefits.

C. Surgery

Surgery is particularly effective in treatment of pure stress incontinence associated with urethrocoele. A variety of surgical techniques for the transvaginal or transabdominal suspension of the bladder neck yield a success rate between 80 and 95 percent in appropriately selected patients with stress incontinence at 1-year followup. Long-term results require study. When incontinence in men is secondary to outflow obstruction and chronic retention is secondary to prostatic enlargement, it is best treated with prostatectomy.

In addition, there are several specialized and more extensive surgical procedures. When incontinence is due to intrinsic sphincter dysfunction, which may occur after the surgical trauma of radical pros-

tatectomy or sphincter denervation, the compressive action of the sphincter is lost. An implantable prosthetic sphincter can restore this compression. Continence is restored in 70 to 90 percent of patients in various series. A complication rate greater than 20 percent includes erosion of the urethra, infection, and mechanical failure. Reoperations are frequently required.

Urethral sling procedures pass a ribbon of fascia or artificial material beneath the urethra. The sling, fixed to the anterior body wall, serves to elevate and compress the urethra, restoring continence in 80 percent of patients. Bladder augmentation with isolated bowel segments will increase bladder capacity and vent excessive bladder pressure. This procedure is limited to certain specific bladder problems such as the contracted bladder of neurologic disease or tuberculosis. Bladder replacement with continent diversion can also be offered to the cystectomy patient.

There are no simple procedures to control bladder instability or sensory urgency. When incontinence is due to a mixture of stress and urge, pharmacologic or behavioral treatment may be employed in conjunction with surgery, but results are not as good as when stress incontinence exists alone.

Selection of patients for surgical procedures depends upon the diagnosis and upon the condition of the patient. The frailty of the patient, the condition of tissues, and the state of nutrition bear on the ability to heal. The severity of symptoms must be considered in relation to the risk the patients must undertake for their surgical correction. Finally, such factors as the durability of the treatment and the incidence of complications must also be considered in choosing a treatment option.

D. Behavioral Techniques

Behavioral techniques increase the patient's awareness of the lower urinary tract and environment and can enhance control of detrusor and pelvic muscular function. Such tech-

niques are participatory, relatively noninvasive, and generally free of side effects, and they do not limit future options. They do require time, effort, and continued practice. Some patients become dry, while a larger number experience important reduction of wetness, and others receive no benefit. Those who appear to benefit most are highly motivated individuals without cognitive deficits. Men and women with stress and urge incontinence have benefitted, whereas patients with severe sphincter damage (such as in post-radical prostatectomy with constant leakage) generally do not benefit.

Behavioral techniques should be offered as a choice to patients who are motivated to put in the time and effort and wish to avoid a more invasive procedure. Commonly employed techniques include:

- Pelvic muscle exercises strengthen the voluntary peri-urethral and pelvic floor muscles, the contraction of which exerts a closing force on the urethra. These techniques have been emphasized for women with stress incontinence but appear to be useful in men as well. Benefit has been reported in 30 to 90 percent of women, but criteria for improvement differ among studies. Patients with mild symptoms may improve most. Continued exercise is required for continued benefit.
- Biofeedback is a learning technique to exert better voluntary control over urine storage. Biofeedback uses visual or auditory instrumentation to give patients moment-to-moment information on how well they are controlling the sphincter, detrusor, and abdominal muscles. After such training, successful patients typically learn to perform the correct responses relatively automatically. Patients with urinary incontinence are trained to relax the detrusor and abdominal muscles and/or contract the sphincter, depending upon the form of incontinence. When used in patients with stress and/or urge inconti-

nence, biofeedback has been shown to result in complete control of incontinence in approximately 20–25 percent of patients and to provide important improvement in another 30 percent. There are two caveats: the degree of improvement is variable, and long-term followup data are not available. It is important to recognize that biofeedback requires sophisticated equipment and training. The benefit of adding biofeedback to pelvic muscle exercise regimens has not been adequately evaluated.

- Bladder training instructs patients to void at regular short intervals, usually hourly during the day, and then at progressively longer intervals of up to 3 hours over a training period of a few to a dozen weeks. Bladder training appears to be effective in reducing the frequency of stress and urge incontinence. Studies have indicated cure rates of 10–15 percent and improvement in the majority of patients.
- Behavioral techniques in the nursing home. For institutionalized elderly, almost any consistent attention to the problem, including bladder training and frequent scheduled checks for dryness appears to reduce incontinence in at least some patients. Another technique applicable in the nursing home is prompted voiding, in which frequent (1 to 2 hourly) checks for dryness are made, reminding the patient to void and praising success.

E. Staging of Treatment

As a general rule, the least invasive or dangerous procedures should be tried first. For many forms of incontinence, behavioral techniques meet this criterion. When behavioral techniques do not achieve the desired result, pharmacologic treatment can be initiated. Clear indications for surgical intervention must be respected, however, and surgical treatment should not be withheld inappropriately. Overflow incontinence due to prostatism and urge in-

continence due to carcinoma of the bladder or prostate must be recognized and treated promptly. After having been informed of surgical and nonoperative options, the patient who is a surgical candidate and wants prompt treatment (e.g., as in the case of stress incontinence) should be operated on. In patients with mixed incontinence, a combination of surgery, behavioral techniques, and pharmacotherapy may be helpful.

F. What Management Techniques Are Appropriate When Treatment Is Not Effective or Indicated?

For patients who have not been successfully treated, management plans must be developed to maximize their well-being. Even when permanent improvement is not expected, techniques such as frequent toileting and reminders may be useful in reducing the impact of the patient's incontinence. Careful evaluation of the timing and pattern of incontinence may suggest helpful changes such as bedtime fluid restriction, provision of easier access to toilet facilities, and temporary or permanent arrangements for protection of the patients, their clothing, and environment.

Currently available modes of protection include absorbent pads or garments, indwelling catheters, and external collection devices such as condom catheters. Absorbent pads or garments provide comfort and convenience when used temporarily in conjunction with therapy; no method is entirely satisfactory for long-term use. For long-term use with incapacitated patients, absorbent materials are expensive, require personnel time, and can be associated with pressure sores when circumstances prevent meticulous attention to prompt changes.

For men, external collection devices are less expensive and less time-consuming for patient and caregiver, but they are associated with increased incidence of urinary tract infection and other complications. Practical external collection devices for women are not generally avail-

able.

Indwelling urethral or suprapubic catheters may be necessary for selected patients, but almost invariably lead to bacteriuria within a few weeks and have been associated with sepsis.

5. What strategies are effect in improving public and professional knowledge about urinary incontinence?

There have been limited efforts to inform the public and professionals about urinary incontinence. The effectiveness of these strategies has not been evaluated. Incontinence education, therefore, must rely on methods that have been used in other areas of health education. Effective strategies to improve public and professional awareness need to be developed, implemented, and evaluated.

Negative societal attitudes about urinary incontinence have been a barrier to increasing public and professional knowledge. The scientific study of incontinence and the dissemination of research findings will help professionals and laypersons realize that loss of continence need not be a condition that is inevitable or shameful.

Strategies for Improving Public Knowledge

Providing accurate information on the management of incontinence to persons with this problem and their families is a challenging and important task. Studies suggest that only half of the people with incontinence report their condition to a physician. Strategies that will reach the largest number of people will be effective in encouraging them to seek professional help. These include informative newspaper and magazine articles, radio and television programs, and special educational programs in senior centers.

One innovative suggestion that deserves consideration is the mandatory labeling of all absorbent products, informing the public that persistent urinary incontinence

should be evaluated and that effective treatments are available.

Strategies for Improving Professional Knowledge

There is an urgent need to educate professionals and paraprofessionals about urinary incontinence.

First and foremost, information on urinary incontinence should be included in the core curricula of undergraduate and graduate professional schools. Schools of nursing should consider the feasibility of educating specialists on incontinence care, who can serve as expert advisers to health care professionals.

To increase practitioners' knowledge of this important condition, continuing education courses focusing on the types of incontinence and appropriate diagnostic measures and treatment should be offered. Professionals most likely to provide care to people with incontinence should be encouraged to attend these courses.

Education on the topic of urinary incontinence should also be a part of the training programs for paraprofessional students such as licensed vocational nurses, nurses aids, and auxiliary workers in the community. Because urinary incontinence is a problem of great magnitude in long-term care settings, special emphasis should be placed on educating nurses aides.

Last, coordinated care for people with incontinence will be facilitated by encouraging alliances among all professionals responsible for caring for people with incontinence.

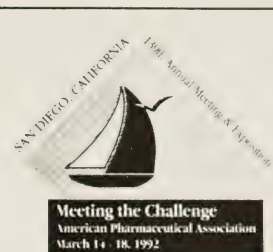
6. What are the needs for future research related to urinary incontinence?

The Consensus Development Conference on Urinary Incontinence in Adults has provided an overview of current knowledge on the etiology, pathophysiology, sequelae, and management of this prevalent clinical problem. Although information on incontinence is increasing, this field has long been ne-

glected, and numerous gaps exist in our knowledge. While many controversies were addressed, numerous questions were identified that await answers and thus serve as the focus for future research directions. These issues will require the collaborative input of investigators from the spectrum of relevant disciplines and the rigorous application of appropriate research principles.

Directions for future research:

- Basic research on the mechanisms underlying the etiology, exacerbation, and response to treatment of specific forms of urinary incontinence and urgency.
- Epidemiologic studies with emphasis on elucidation of risk factors for development of urinary incontinence, its occurrence in specific populations (particularly males and nonwhites), and the natural history of the various clinical and physiologic subtypes.
- Studies of strategies to prevent urinary incontinence.
- Randomized clinical trials, including longitudinal studies in well-specified populations, of algorithms for the systematic assessment of patients with incontinence and of specific behavioral, pharmacologic, and surgical treatment, either alone or in combination.
- Development of new therapies, including pharmacologic agents with greater specificity for the urinary tract and new behavioral and surgical strategies and other innovative techniques, including electrical stimulation.



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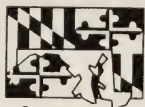
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Practicing Within the Law *One Pharmacist's Story*

Earl M. Towers, P.D

It seems like it is becoming too common today to see headlines publicizing criminal proceedings against pharmacists for illegal distribution of controlled substances. We see articles in the newspapers with headlines such as "Pharmacist Charged With Illegal Dispensing", "Pharmacist Admits to Illegal Distribution or Selling of Controlled Substances" and "Physician and Pharmacist Convicted in Prescription-Fraud Scheme". These headlines all convey a common theme that our profession of pharmacy is somehow being betrayed.

Unfortunately, there are some pharmacists who, for the purpose of personal gain, intentionally violate the laws pertaining to controlled substances. This is an exception to the typical pharmacy practice, however, because these pharmacists are few in number. It is important to point out that a pharmacist who violates the law pertaining to controlled substances is a criminal, regardless of the reasons.

This is where my story begins and I hope it may help some other pharmacist who may be in a similar situation.

I have been a registered pharmacist in Maryland for over 23 years and have owned my own pharmacy since 1980. I have always considered myself to be a dedicated pharmacist and have tried to promote the profession whenever possible such as speaking to local community groups and participating in drug abuse programs.

On October 1, 1990 I was arrested and charged with dispensing of prescription drugs (CDS) without a prescription. I was immediately released on bail, but my pharmacy license and pharmacy permit were both suspended by the Maryland Board of Pharmacy. The DEA also suspended the registration of my pharmacy to handle controlled substances.

I had been selling prescription drugs -- including Dilaudid and Percodan -- to three individuals for money, but not for the street value of the drugs that I possibly could have gotten. All of these people had made threats against my life and my family, including my wife and daughters.

This all started out when I tried to help someone who I thought was in trouble. I had given him a few tablets over the weekend until he could get a new prescription. He had a prescription bottle for Valium which had no refills and made a desperate plea for enough medication

until he could see his physician. That was my first mistake and one thing lead to another.

Before I knew it, two other individuals had shown up and threatened me and my family if I didn't sell them some controlled substances. Over a period of time there were some serious threats made -- even with hand grenades and the mentioning of motorcycle gangs and drug connections in Philadelphia and New York. I know I should have simply said no and gone to the police, but the fact is that I didn't. Instead I found myself getting more involved. The local drug task force received information from an informant and after a period of surveillance and investigation, I was arrested.

*I was arrested and charged with
dispensing... CDS without a prescription.*

I try to think back as to how I got involved in a situation such as this and many reasons float through my mind. In the beginning, maybe I fell prey to trickery and deceit, but that was no excuse.

Why would I allow a situation like this to happen? I knew my responsibilities under the laws pertaining to controlled substances, but for whatever reason, I began to take a cavalier approach toward fulfilling these duties. It could have simply started with requests to refill a prescription where no refills are authorized or to refill a prescription earlier than indicated. I suppose that when one tends to bend the law a little, it leads to other things and one becomes careless and negligent.

I started selling the drugs because of the threats to my family, but I also was taking the money. Maybe greed played a part. I was afraid to go the police although I thought about it many, many times. I knew I was in trouble with the law, the Board of Pharmacy and the DEA, regardless of what else happened. When I was arrested, there was a great sense of relief on my part. I was thankful it was over, regardless of the consequences.

Continued on page 26....

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Scott Rickards

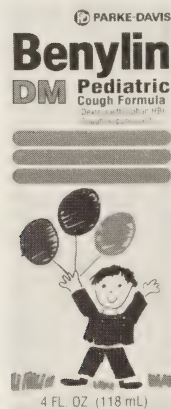
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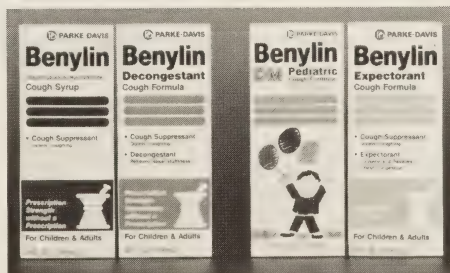
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Practicing Within the Law

Continued

After six months with no income and costly legal fines, I decided to accept a plea bargain. I decided against my right to have a jury trial because I didn't want to put my family through any more humiliation or despair and I wanted to get everything over with as soon as possible. In my opinion the press was very unfair and as usual my side was not presented at all. Many of the facts and even some of the statements were taken out of context or were just not true and thus made the situation sound worse.

My plea bargain consisted of a \$20,000.00 fine, agreement to sell my pharmacy and a maximum sentence of 3 years with suspension and probation a possibility. I pleaded guilty to a felony - one count of distribution of Dilaudid. I also took an alford plea which means I thought it was in my best interest to accept the plea bargain since I was guilty, but only because of mitigating circumstances such as the threats to myself and my family.

The judge said he was sending a strong message to other pharmacists and also to drug dealers who declare war on community pharmacists

At my criminal hearing I received the maximum sentence allowable under my plea bargain agreement -- a sentence of 10 years with all but 3 years suspended. I also received a probation period after my parole of 5 years with an additional fine of \$3,000.00 per year for a total of \$15,000.00. I am currently serving my sentence at the minimum security section of Eastern Correctional Institution in Westover, Maryland and I am eligible for parole in December.

I was hoping for a suspended sentence with probation, but the judge said he was sending a strong message to other pharmacists and also to drug dealers that they couldn't just declare war on community pharmacists. I made a mistake and I am willing to pay for it, especially if it will help our profession in dealing with the drug abuse problem.

I believe that I was a victim of circumstance and we cannot always control the circumstances that we find ourselves involved in. What we can control is the way we respond to those circumstances and how we handle them. Many times we let our emotions such as stress, anger and fear control our reactions. I did not have the strength or courage to respond to my situation in the proper way. I just sort of rolled over and played along, disregarding my

professional responsibilities. The law works as hard to obtain a conviction, regardless of the circumstances as does the pharmacist to obtain an acquittal.

By violating the law, pharmacists face the possibility of disciplinary action which could include loss or suspension of their licenses and also force closure of their pharmacies. A criminal prosecution and conviction for the violation of controlled substance laws is often just the beginning of a long, traumatic and costly process. It is also important to point out that a criminal conviction will, most likely, affect the relationship of the pharmacist with their family and professional colleagues and thus their standing in the community and profession.

We must realize that the repercussion for violation of controlled substance laws extend beyond imprisonment and financial loss such as fines and legal fees. Pharmacists cannot afford to act unprofessionally in their responsibilities of handling controlled substances, the risk of losing your professional license, career, source of income and even family, are all very real possibilities.

It should be the goal of every pharmacist to maintain full and voluntary compliance with the laws of controlled substances. If you are violating the laws pertaining to CDS, you will get caught eventually. Believe me, it is definitely not worth the risk. Besides your moral obligation to act responsibly and professionally, remember that someone may be watching and listening.

I realize that every pharmacist and also the profession suffers when we see the types of headlines I mentioned in the beginning. I am very sorry for that, but that does not change the fact that I violated the law. Through all the things that have happened to me over the past year, I just hope that I might be given another chance to work at my chosen profession. I am very proud of the pharmacy profession and I look forward to working again as a pharmacist and being an asset to the profession and to the community. ■



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Abbott Laboratories has announced that *Biaxin* (clarithromycin) a new prescription oral antibiotic is now available. Combining the best attributes—coverage, safety, and bactericidal activity—of both the macrolide and oral beta-lactam antibiotics, the new product is indicated for the treatment of respiratory tract and skin and skin structure infections.



Ciba-Geigy was recently given clearance by the FDA to market *Aredia* (pamidronate disodium) for the treatment of moderate or severe hypercalcemia of malignancy in patients with or without bone metastases.

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SmithKline Beecham Pharmaceuticals has received approval from the FDA for a new 30 gram size of *Bactroban* (mupirocin) ointment. Bactroban is indicated for the treatment of dermatological infections caused by *staphylococcus aureus*, *streptococcus pyogenes*, and beta-hemolytic streptococci.



Syntex has introduced *Ticlid* (ticlopidine) available in 250mg strength, 30 tablet size packages. The product is a platelet antiagregant used in the prevention of threatened and recurrent strokes.

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Continuing Education Quiz

The Maryland Pharmacist

DECEMBER 1991

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by April 30, 1992. A continuing education certificate for one contact credit will be mailed to you within 30 days. Please type or print clearly.

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Is this program used to meet your mandatory CE? ☐ Yes ☐ No

Did this article achieve its stated objectives? ☐ Yes ☐ No

How long did it take you to complete the program? _____ minutes

Urinary Tract Infections

1. The abnormality that most commonly disposes older males to urinary tract infection is:
 - a. atherosclerosis.
 - b. meatal stenosis.
 - c. prostatic hypertrophy.
 - d. renal calculi.
2. The drug that exerts its antibacterial activity by being converted into formaldehyde in acidic urine is:
 - a. Cipro.
 - b. Macrodantin.
 - c. Noroxin.
 - d. Mandelamine.
3. Of the following, the most common cause of hospital-acquired urinary tract infection is:
 - a. improper catheterization.
 - b. overgrowth of intestinal bacteria.
 - c. poor sanitary conditions.
 - d. unsterile surgical equipment.
4. An infection of the urinary bladder is referred to as:
 - a. cystitis.
 - b. diverticulitis.
 - c. pyelonephritis.
 - d. urethritis.
5. Cipro and Noroxin are members of the chemical class of anti-infectives called:
 - a. cephalosporins.
 - b. nitrofurantoin.
 - c. quinolones.
 - d. sulfonamides.
6. All of the following information for consumers about OTC testing products for UTIs is correct EXCEPT:
 - a. "Be sure the container used to collect the urine sample is clean and dry, and perform the test as soon as possible after voiding."
 - b. "Perform the test on urine collected in the evening before going to bed to assure capturing all possible bacteria."
 - c. "Be sure to perform the test on three consecutive days."
 - d. "Keep the test strip in the foil wrapper until just prior to testing the urine."
7. Of the following, the most common cause of hospital-acquired urinary tract infection is:
 - a. *Escherichia coli*.
 - b. *Staphylococcus aureus*.
 - c. *Pseudomonas aeruginosa*.
 - d. *Streptococcus viridans*.
8. Which of the following is a major reason why urinary tract infections are more common in women than men?
 - a. Bacterial growth is enhanced by the slightly more acidic urine of women.
 - b. Bacterial growth is enhanced by the slightly more alkaline urine of women.
9. The advice "Take the dose with food" is *most* appropriate for which of the following drugs?
 - a. Noroxin
 - b. Macrodantin
10. Of the following, the most common cause of community-acquired urinary tract infection is:
 - a. *Escherichia coli*.
 - b. *Staphylococcus aureus*.
 - c. *Pseudomonas aeruginosa*.
 - d. *Streptococcus viridans*.

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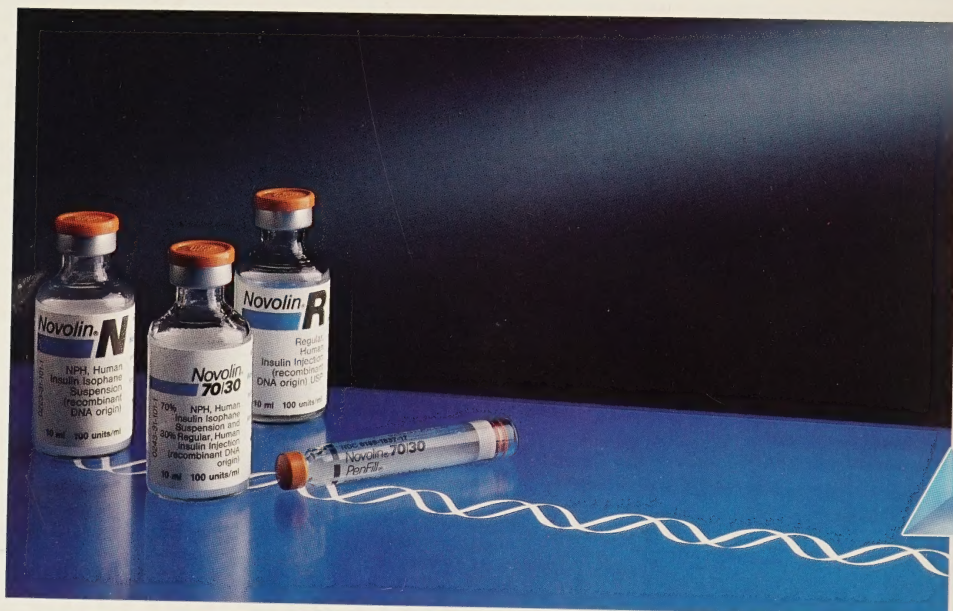


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